Exhibit A

THE HONORABLE JOHN H. CHUN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

SHENZHEN ROOT TECHNOLOGY CO., LTD., HONG KONG LUTE TECHNOLOGY CO., LIMITED, AND SHENZHEN CONGLIN E-COMMERCE CO., LTD., Plaintiffs, v. CHIARO TECHNOLOGY Ltd., Defendant.	Case No. 2:23-cv-631 **CHIARO TECHNOLOGY LTD.'S AMENDED COUNTERCLAIMS**
CHIARO TECHNOLOGY LTD., Counterclaim Plaintiff, v. SHENZHEN ROOT TECHNOLOGY CO., LTD., HONG KONG LUTE TECHNOLOGY CO., LIMITED, SHENZHEN CONGLIN E-COMMERCE CO., LTD, SHENZHEN ROOT E-COMMERCE CO., LTD., SHENZHEN TPH TECHNOLOGY CO., LTD., SHENZHEN LUTEJIACHENG NETWORK TECHNOLOGY CO., LTD., and SHENZHEN JINRUIHANG TECHNOLOGY CO., LTD., SHENZHEN XITAO NETWORK TECHNOLOGY CO., LTD., Counterclaim Defendants.	

Defendant/Counterclaim Plaintiff Chiaro Technology Ltd. (“Defendant” or “Elvie”) hereby submits its Amended Counterclaims to Plaintiff’s Amended Complaint for Declaratory Judgment and Other Relief (“Amended Complaint”) filed by Shenzhen Root Technology Co., Ltd. and its affiliates Hong Kong Lute Technology Co., Limited and Shenzhen Conglin e-Commerce Co., Ltd. (collectively “Plaintiffs”).

AMENDED COUNTERCLAIMS

Elvie asserts the following amended counterclaims against Counterclaim Defendants Shenzhen Root Technology Co., Ltd. Hong Kong Lute Technology Co., Ltd., and Shenzhen TPH Technology Co., Ltd. (collectively, “Plaintiffs”), as well as Shenzhen Root E-Commerce Co., Ltd., Shenzhen Lutejiacheng Network Technology Co., Ltd., and Shenzhen Xitao Network Technology Co., Ltd.

Nature of the Counterclaims

1. This counterclaim is for willful patent infringement of U.S. Patent Nos. 11,357,893 (the “’893 patent”), 11,413,380 (the “’380 patent”), 11,813,381 (the “’381 patent”) and 11,806, 454 (the “’454 patent”) (collectively, the “Asserted Patents”) and breach of contract under Washington common law.

2. Elvie alleges that Momcozy’s S9, S9 Pro, S12, S12 Pro, M1, M5, V1, and V2 products (collectively, the “Accused Products”) infringe at least one of the Asserted Patents.

3. Elvie alleges that each of Momcozy’s S9, S9 Pro, S12, S12 Pro, M1, and M5 products (collectively, the “Accused Products”) infringe the ’893 and ’380 patents.

4. Elvie alleges that the Momcozy S9, S9 Pro, S12, and S12 Pro additionally infringe the ’381 patent.

5. Elvie alleges that the Momcozy V1 and V2 infringe the ’454 patent.

The Parties

6. Elvie is a company incorporated under the laws of England and Wales and located at 63-66 Hatton Garden, Second Floor, London, EC1N 8LE, United Kingdom.

7. On information and belief, Shenzhen Root Technology Co., Ltd. ("Shenzhen Root") is a company formed in China with the address 2F2-201 Shenzhou Computer Building, Curie Madame Avenue, Longgang District, Shenzhen, China. On information and belief, Shenzhen Root is managed by Pan Silin as the General Manager and Executive Director and Pan Zhenxiang as the supervisor. Shenzhen Root is assigned the United Social Credit Code ("USCC") of 91440300MA5FX6EH4G.

8. On information and belief, Hong Kong Lute Technology Co., Limited ("Hong Kong Lute") is a foreign corporation that is registered in the state of Colorado under the address 18121 E Hampden Ave, Unit C, #1007, Aurora, CO 80013. On information and belief, Pan Silin is listed as the sole Officer of Hong Kong Lute. Hong Kong Lute is formed under the laws of Hong Kong and has its principal place of business at Room 02, 21F Shek Kwan Commercial Building, 38 Bi Street, Yau Ma Tei, Kowloon, Hong Kong. Hong Kong Lute is assigned the company code of 3069869.

9. As Plaintiffs have admitted, Shenzhen Root is a parent of Hong Kong Lute. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 2.

10. As Plaintiffs have admitted, Hong Kong Lute is a subsidiary of Shenzhen Root. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 2.

11. On information and belief, Shenzhen Conglin E-Commerce Co., Ltd. ("Shenzhen Conglin") is a company formed in China with the address 401D81, Leizhen Building, No. 40, Fuming Road, Futian District, Shenzhen, China. Shenzhen Conglin is managed by Gong Shaocong and Duan Shuyu. On information and belief, Shenzhen Conglin is assigned the USCC of 91440300MA5H3EYN0R.

12. As Plaintiffs have admitted, Shenzhen Root is a parent of Shenzhen Conglin, which is owned in trust for the benefit of and is controlled by Shenzhen Root. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 2.

13. As Plaintiffs have admitted, Shenzhen Conglin is a subsidiary of, is owned in trust for the benefit of, and is controlled by Shenzhen Root. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 2.

14. On information and belief, Shenzhen TPH Technology Co., Ltd. ("Shenzhen TPH") is a company formed in China with the address 2F, Building 29, Lianchuang Technology Park II, Longgang District, Shenzhen, China. On information and belief, Shenzhen TPH is managed by Zianzi Chen and Yanhong Cai. According to Shenzhen E-Commerce and Hong Kong Dian Ying Industry Co. Ltd, Shenzhen TPH is responsible for the manufacture and sale to Shenzhen E-Commerce and Hong Kong Dian Ying Industry Co. Ltd of at least the S9, S12, and M1 breast pumps. On information and belief, Shenzhen TPH is assigned the USCC of 914403003352154174.

15. On information and belief, Shenzhen Root E-Commerce Co., Ltd. ("Shenzhen E-Commerce") is a company formed in China with the address 2F2-208 Shenzhou Computer Building, Curie Madame Avenue, Longgang District, Shenzhen, China. On information and belief, Shenzhen E-Commerce recently changed its name to Shenzhen Yuyou Technology Co., Ltd. On information and belief, Shenzhen E-Commerce is managed by Yongge Zheng and Geyu Zheng. On information and belief, Shenzhen E-Commerce is assigned the USCC of 91440300359646166T.

16. On information and belief, Shenzhen Lutejiacheng Network Technology Co., Ltd. ("Lutejiacheng") is a company formed in China with the address 2F2-201 Shenzhou Computer Building, Curie Madame Avenue, Longgang District, Shenzhen, China. On information and belief, Lutejiacheng also goes by the name "Shenzhen Lutejiacheng Technology Co., Ltd." On information and belief, Lutejiacheng is managed by Pan Silin and Pan Zhenxiang. On information and belief, Lutejiacheng is assigned the USCC of 91440300MA5FX6EH4G.

17. On information and belief, Shenzhen Jinruihang Technology Co., Ltd. ("Jinruihang") is a company formed in China with the address Room 204, Building 59, Vanke Donghai'an, No. 216 Huanbi Road, Donghai'an, No. 216 Huanbi Road, Donghai'an Community,

Meisha Street, Yantian District, Shenzhen, China. On information and belief, Jinruihang is assigned the USCC of 91440300MA5GKP331A.

18. On information and belief, Shenzhen Xitao Network Technology Co., Ltd. ("Xitao") is a company formed in China with the address 2F2-209, Shenzhou Computer Building, Curie Madame Avenue, Longgang District, Shenzhen, China. On information and belief, Xitao is managed by Zhenxiang Pan. On information and belief, Xitao is assigned the USCC of 91440300MA5DCDL377.

19. As Plaintiffs have admitted, Shenzhen Root is a parent of Jinruihang. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 2.

20. As Plaintiffs have admitted, Jinruihang is a subsidiary of Shenzhen Root. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 2.

21. As Plaintiffs have admitted, all shares of Jinruihang are owned by Tao Jin on behalf of and for the benefit of Shenzhen Root. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 2.

22. On information and belief, Elvie is aware of two other entities, Hong Kong Dian Ying Industry Co., Ltd. and Smartlin, which may be entities separate from the Counterclaim Defendants and involved in the offer for sale, sale, and/or importation of the Accused Products.

Jurisdiction and Venue

23. This is an action for patent infringement under 35 U.S.C. § 271 and breach of contract claims under Washington common law.

24. This Court has subject matter jurisdiction pursuant to 35 U.S.C. § 271 for Elvie's claims of patent infringement arising under federal law. This Court has supplemental jurisdiction of Elvie's breach of contract claim pursuant to 28 U.S.C. § 1367, because such claims arise from the same set of operative facts and are so related to the claim arising from Elvie's claim of patent infringement. The Court's exercise of supplemental jurisdiction would promote judicial

economy, convenience, fairness, and avert the risk of inconsistent adjudications of the same issues of law and fact.

25. On information and belief, Shenzhen Root, Hong Kong Lute, Shenzhen Conglin, Lutejiacheng, Jinruihang, Xitao, and Shenzhen E-Commerce operate in the United States to sell the Accused Products through the brand name "Momcozy" and are related to the entities that represented Momcozy in the APEX Proceeding.

A. This Court has Personal Jurisdiction Over Shenzhen Root, Hong Kong Lute, and Shenzhen Conglin

26. Counterclaim Defendants Shenzhen Root, Hong Kong Lute, and Shenzhen Conglin have availed themselves of this forum in this action and are therefore subject to personal jurisdiction in this district. *See* Dkt # 54.

27. On information and belief, Shenzhen Root, Hong Kong Lute, and Shenzhen Conglin sell the Accused Devices in the United States under the tradename "Momcozy." *See* Dkt. #29 at 33; Dkt. #39, ¶¶ 5, 10.

28. On information and belief, Shenzhen Root is an entity responsible for importing, offering for sale, and selling the Accused Products in the United States. *See* Dkt. #39, ¶ 2.

29. On information and belief, Shenzhen Root sells the Accused Products online, including at momcozy.com and Amazon.com. *See* Dkt. #39, ¶¶ 7, 10.

30. As Plaintiffs have admitted, Shenzhen Root is responsible for the design, development, operation, manufacture, testing, marketing, distribution, sale, and importation into the United States of at least the S12 Pro products imported into the United States, either directly or through its subsidiaries. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 1.

31. On information and belief, Hong Kong Lute is an entity responsible for importing, offering for sale, and selling the Accused Products in the United States. *See* Dkt. #29 at 33.

32. On information and belief, Hong Kong Lute sells the Accused Products online, including at momcozy.com and Amazon.com. *See* Dkt. #29 at 33.

33. By May 17, 2022, Hong Kong Lute, along with Shenzhen Lute Jiacheng Technology Co., Ltd., was listed on Momcozy.com as the entities behind Momcozy. *See* Dkt. #29 at 33. On information and belief, the listed Shenzhen Lute Jiacheng Technology Co., Ltd. is the same entity as Shenzhen Lutejiacheng Network Technology Co., Ltd. ("Lutejiacheng"). *See* Dkt. #39, ¶¶ 2–3.

34. As Plaintiffs have admitted, Hong Kong Lute participated in the distribution and importation into the United States of the S12 Pro products. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 1.

35. As Plaintiffs have admitted, Hong Kong Lute took possession of the S12 Pro products, including in Hong Kong, and caused those products to be imported into the United States. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 1.

36. On information and belief, Shenzhen Conglin is an entity responsible for importing, offering for sale, and selling the Accused Products in the United States. *See* Dkt. #39, ¶ 10.

37. On information and belief, Shenzhen Conglin sells the Accused Products online, including at momcozy.com and Amazon.com. *See* Dkt. #39, ¶ 10.

38. As Plaintiffs have admitted, Shenzhen Conglin was involved in the distribution, marketing, and sales of S12 Pro products, including sales of those products in the United States via Amazon.com after importation into the United States. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 1.

39. As Plaintiffs have admitted, Shenzhen Conglin marketed and sold the S12 Pro products via listings with Amazon.com. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 1.

40. Therefore, this Court has personal jurisdiction over Shenzhen Root, Hong Kong Lute, and Shenzhen Conglin.

B. This Court has Personal Jurisdiction Over Shenzhen TPH

41. On information and belief, based at least upon correspondence received from Plaintiffs' counsel, Shenzhen TPH is the manufacturer of the S9 and S12 breast pumps on behalf of Momcozy. Dkt. #29 at 170–71; Exhibits 1-2, FDA Website.

42. On information and belief, based at least upon correspondence received from Plaintiffs' counsel, Shenzhen TPH has indemnified Shenzhen Root E-Commerce Co., Ltd. and Hong Kong Dian Ying Industry Co. Ltd. for any patent infringement of at least the S9, S12, and M1 breast pumps. Dkt. #29 at 170–71.

43. On information and belief, Shenzhen TPH knowingly manufactured and sold, at least, the S9, S12, and M1 breast pumps to the entity called "Momcozy," or entities working on behalf of "Momcozy," knowing that they would be imported into and sold in the United States, including the State of Washington.

44. On information and belief, Shenzhen TPH manufactures and sells to Counterclaim Defendants at least the S9, S12, and M1 breast pumps, knowing that the products will be imported into and sold in the United States.[1]

45. On information and belief, Shenzhen TPH has indemnified Plaintiffs for charges of patent infringement against at least the S9, S12, and M1 breast pumps. Dkt. #29 at 170.

46. On information and belief, Shenzhen TPH is aware of Elvie's patents. *See* Dkt. #29 at 170–71.

47. On information and belief, Shenzhen TPH has informed Plaintiffs that the products it manufactures do not infringe any intellectual property, including Elvie's patents. *See* Dkt. #29 at 170–71.

48. Therefore, this Court has personal jurisdiction over Shenzhen TPH.

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[1] According to Pan Silin's declaration, the S12 Pro is not manufactured by Shenzhen TPH. *See* Dkt. #35 at 5. Elvie has propounded discovery regarding the correct identity of the manufacturer of each of the Accused Products.

C. This Court has Personal Jurisdiction Over Shenzhen E-Commerce

49. On information and belief, Shenzhen E-Commerce sells the Accused Devices in the United States under the tradename "Momcozy." *See, e.g.*, Dkt. #29 at 27, 32.

50. On information and belief, Shenzhen E-Commerce is an entity offering for sale and selling Momcozy products, including the Accused Products, in the United States, including this District, through, at least, its online website, momcozy.com. *See* Dkt. #29 at 27, 32.

51. By at least November 29, 2020, Shenzhen E-Commerce was listed on Momcozy.com as the entity behind Momcozy. *See* Dkt. #29 at 27, 32.

52. By at least March 3, 2022, Shenzhen E-Commerce and Hong Kong Dian Ying Industry Co., Limited were listed on Momcozy.com as the entities behind Momcozy. *See* Dkt. #29 at 32.

53. Therefore, this Court has personal jurisdiction over Shenzhen E-Commerce.

D. This Court has Personal Jurisdiction Over Lutejiacheng

54. On information and belief, Lutejiacheng sells the Accused Devices in the United States under the tradename "Momcozy." *See* Ex. 22, FDA Lutejiacheng Registration.

55. On information and belief, Lutejiacheng is an entity involved in the sale and importation of the Accused Products into the United States.

56. By May 17, 2022, Shenzhen Lute Jiacheng Technology Co., Ltd., along with Hong Kong Lute, was listed on Momcozy.com as the entities behind Momcozy. *See* Dkt. #29 at 33. On information and belief, the listed Shenzhen Lute Jiacheng Technology Co., Ltd is the same entity as Shenzhen Lutejiacheng Network Technology Co., Ltd. ("Lutejiacheng").

57. On information and belief, Lutejiacheng is managed by Pan Silin, the alleged sole founder and CEO of Shenzhen Root Technology Co., Ltd. Dkt. #19, ¶ 1.

58. On information and belief, Momcozy's U.S. trademark registration for the mark "Momcozy" was registered under Lutejiacheng's name. *See* Dkt. #35, ¶ 8; Dkt. #35, Ex. 29 at 1.

59. On information and belief, Lutejiacheng registered the Accused Products with the FDA in order to sell the Accused Products within the United States. *See* Exhibit 22, FDA

Lutejiacheng Registration. On information and belief, Lutejiacheng offers for sale, sells, and/or imports the Accused Products in the United States.

60. On information and belief, Lutejiacheng made the Accused Products available for sale in the United States with knowledge that the Accused Products infringed Elvie's patents. *See* Dkt. #22, ¶ 12.

61. On information and belief, Lutejiacheng has made the devices available for purchase in the United States by registering the device with the FDA in the United States.

62. Therefore, this Court has personal jurisdiction over Lutejiacheng.

E. This Court has Personal Jurisdiction Over Jinruihang

63. On information and belief, Jinruihang is a subsidiary of Shenzhen Root.

64. As Plaintiffs have admitted, Jinruihang is a post-importation distributor through Amazon.com of, at least, the S12 Pro products. *See* Plaintiffs' August 7, 2023 Responses to Defendant's First Set of Interrogatories, Interrogatory No. 1.

65. Based on representations from Plaintiffs' counsel, Elvie understands that Jinruihang is the entity that sells the Momcozy products on Amazon.com through the United States, including this District, under the name "Jinruixingkeji." *See* Dkt. #39, ¶ 10.

66. On information and belief, Jinruihang sells the S12 Pro products throughout the United States, including this District, through online marketplaces such as Amazon.com. *See* Dkt. #39, ¶ 10.

67. Therefore, this Court has personal jurisdiction over Jinruihang.

68. Venue is proper in this judicial district under 28 U.S.C. §§ 1391, 1400, and as a result of Counterclaim Defendants' choice of forum in filing this action.

F. The Court has Personal Jurisdiction Over Xitao

69. On information and belief, Xitao is an entity offering for sale and selling Momcozy products, including the Accused Products, in the United States, including this District, through, at least, its online website on Alibaba.com.

70. Plaintiffs have admitted during discovery that Xitao is a post-importation distributor of, at least, the S12 Pro, S12, S9 Pro, S9, M1, and M5 products within the United States.

71. Therefore, this Court has personal jurisdiction over Xitao.

72. Venue is proper in this judicial district under 28 U.S.C. §§ 1391, 1400, and as a result of Counterclaim Defendants' choice of forum in filing this action.

Background

A. Elvie's Innovations in Women's Health

73. Elvie was founded in April 2013 by Tania Boler, an internationally recognized women's health expert, with the mission to revolutionize women's healthcare by developing smarter, "female first" technology that improves the health and lives of women.

74. Since 2013, Elvie has innovated, developed, and sold products in women's healthcare categories, which have been overlooked for many years, including breast pumps and pelvic floor health. The first product to launch, Elvie Trainer, is an award-winning Kegel trainer and app that helps women strengthen the pelvic floor. Its second product, Elvie Pump, is the world's first silent, wearable breast pump. Elvie Pump launched during the 2018 London Fashion Week when Valeria Garcia walked the runway while wearing the Elvie Pump.

75. Prior to the launch of the Elvie Pump, the breast pump industry had remained largely stagnant for almost half a century, with breast pumps being loud, big, and typically requiring an electrical outlet. Elvie invested substantial time and resources to investigate the issues women faced when using existing breast pumps. With its in-bra, discreet, silent, and wireless design, the Elvie Pump changed the way that mothers can breastfeed to meet the demands of their increasingly busier lives.

76. In addition, Elvie Pump allows mothers to control the pump through a phone application. This allows mothers to customize the pump to fit their needs while giving them the freedom to pump whenever and wherever they would like.

77. Noted as one of "the biggest innovation[s] in pumping technology of the past 100 years," *See Elvie*, Core77 Design Awards 2019, https://designawards.core77.com/health-wellness/85273/Elvie (last accessed May 10, 2023), Elvie Pump's trailblazing technology includes a coin-sized pump, sleek design, and the ability to run quietly and discreetly.

78. The Elvie Pump has won over 20 awards for its innovation including International Design Awards, Mumsnet Awards, Dezeen Awards, Baby Magazine Awards, The Red Dot Awards and Good Design Awards amongst others. *See* Ex. 3, Achievements at Elvie + Chiaro.

79. For example, in 2019, TIME named the Elvie Pump as one of the "Best Inventions of 2019" (Exhibit 4); the Core77 Design Awards named the Elvie Pump as a runner up in the category of Health & Wellness (Exhibit 5); and Dezeen named the Elvie Pump the "Wearable Design of the Year." (Exhibit 6). In 2020, the European Centre awarded the Elvie Pump the 'Good Design Award." (Exhibit 7). Furthermore, in 2022, Forbes named the Elvie Pump the "Best Wearable Breast Pump." (Exhibit 8).

80. In light of the Elvie Pump's groundbreaking technology and popularity, copycat devices (such as Momcozy's S12 Pro device) began appearing in the marketplace in the past several years. These devices are typically sold at a much lower price point than the Elvie Pump partly because, unlike Elvie, the manufacturers of these devices did not have to invest in extensive research & development, nor do they maintain 'hospital-grade' quality.

81. In order to protect its pioneering technology, Elvie applied for and received numerous patents covering its innovative breast pump design and architecture.

82. Elvie began filing patent applications on its design and architecture before Counterclaim Defendants ever sold a single breast pump.

B. The Asserted Patents

83. On June 14, 2022, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued U.S. Patent No. 11,357,893 ("the '893 patent"), entitled, "Breast Pump System." A true and correct copy of the '893 patent is attached hereto as Exhibit 23. The '893 patent was exclusively licensed to Elvie, and Elvie possesses the exclusive right of recovery for

any past, present, or future infringements of the ’893 patent, including equitable relief and damages.

84. The ’893 patent claims priority to a number of Great Britain patent applications with priority dates as early as June 15, 2017. The ’893 patent issued from U.S. Patent Application No. 17/203,050 (the “’050 application”), which was filed on March 16, 2021. The ’050 application is a continuation of U.S. Patent Application No. 17/181,057 (the “’057 application”), which was filed on February 22, 2021. The ’057 application is a continuation of U.S. Patent Application 16/009,547 (the “’547 application”), which was filed on June 15, 2018 and issued as U.S. Patent No. 10,926,011.

85. On August 16, 2022, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued U.S. Patent No. 11,413,380 (the “’380 patent”), entitled, “Breast Pump System.” A true and correct copy of the ’380 patent is attached hereto as Exhibit 24. The ’380 patent was exclusively licensed to Elvie, and Elvie possesses the exclusive right of recovery for any past, present, or future infringements of the ’380 patent, including equitable relief and damages.

86. The ’380 patent claims priority to a number of Great Britain patent applications with priority dates as early as June 15, 2017. The ’380 patent issued from U.S. Patent Application No. 17/203,327 (the “’327 application”), which was filed on March 16, 2021. The ’327 application is a continuation of U.S. Patent Application No. 17/181,057 (the “’057 application”), which was filed on February 22, 2021. The ’057 application is a continuation of U.S. Patent Application No. 16/009,547 (the “’547 application”), which was filed on June 15, 2018 and issued as U.S. Patent No. 10,926,011.

87. On November 14, 2023, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued U.S. Patent No. 11,813,381 (the “’381 patent”) entitled “Breast Pump System.” A true and correct copy of the ’381 patent is attached hereto as Exhibit 26. The ’381 patent was exclusively licensed to Elvie, and Elvie possesses the exclusive right of

recovery for any past, present, or future infringements of the ’381 patent, including equitable relief and damages.

88. The ’381 patent claims priority to a number of Great Britain patent applications with priority dates as early as June 15, 2017. The ’381 patent issued from U.S. Patent Application No. 17/203,292 (the “’292 application”), which was filed on July 8, 2021. The ’292 application is a continuation of U.S. Patent Application No. 17/181,057 (the “’057 application”), which was filed on February 22, 2021. The ’057 application is a continuation of U.S. Patent Application No. 16/009,547 (the “’547 application”), which was filed on June 15, 2018 and issued as U.S. Patent No. 10,926,011.

89. The ’893, ’380, and ’381 patents’ priority date of June 15, 2017, is well before Momcozy first entered the market in 2019. *See* Dkt #54, ¶ 3.

90. On November 7, 2023, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued U.S. Patent No. 11,806,454 (the “’454 patent”) entitled “Wearable Breast Pump System.” A true and correct copy of the ’454 patent is attached hereto as Exhibit 25. The ’454 patent was exclusively licensed to Elvie, and Elvie possesses the exclusive right of recovery for any past, present, or future infringements of the ’454 patent, including equitable relief and damages.

91. The ’454 patent claims priority to Great Britain patent application number 2004395 with a priority date as early as March 26, 2020. The ’454 patent issued from U.S. Patent Application No. 18/148,864 (the “’864 application”), which was filed on May 25, 2023. The ’454 application is a continuation of U.S. Patent Application No. 17/907,347 (the “’347 application”), which was filed on March 25, 2021.

92. The ’454 patent’s priority date of March 26, 2020 is well before Momcozy first sold the V1 and V2 products in the United States.

C. Momcozy's Unlawful Conduct

1. The Accused Products

93. Seeing the success that Elvie achieved through its wearable breast pump inventions, Counterclaim Defendants began manufacturing, importing, and selling the Accused Products, which copy Elvie's architecture. Counterclaim Defendants make, use, sell, and offer for sale these breast pumps under the "Momcozy" name, including the S9, S9 Pro, S12, S12 Pro, M1, M5, V1, and V2 models.[2]

94. Counterclaim Defendants sell the Accused Products through online marketplaces, such as Amazon.com, Walmart.com, and on the Momcozy website. In part because Counterclaim Defendants merely copied Elvie's architecture and did not—and do not—invest the time and resources to develop an innovative product that Elvie did and continues to do, Counterclaim Defendants are able to make and sell the Accused Products at a much lower price point than Elvie.

95. Owing to their late entry into the marketplace using Elvie's by-then-known architecture, the Accused Products have not garnered the industry praise that Elvie's products did years before. Instead, Counterclaim Defendants tout their Amazon buyer reviews that, not surprisingly, focus merely on Momcozy's relatively lower prices.[3]

96. Forced to address Momcozy's copying, in June 2022, Elvie attempted to resolve the issue without Court action by sending a cease and desist letter to the entities, "Shenzhen Root E-Commerce Co., Ltd." and "Hong Kong Dian Ying Industry Co., Ltd." regarding Momcozy's sales of the S9, S12, and M1 Breast Pumps, that infringed upon Elvie's Patents, including the '893 patent. *See* Dkt. #1, Ex. 2 at 2–3. These entities were listed on the Momcozy website's

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[2] To the extent Momcozy introduces additional products, Elvie reserves the right to obtain discovery on those products and further identify them as Accused Products. For example, Momcozy's website references an S10 product, but it is not currently available for purchase.

[3] It is also well known that Amazon buyer reviews are easily manipulated. *See, e.g.*, Ex. 9, https://www.bloomberg.com/news/articles/2021-08-18/amazon-amzn-cracks-down-on-fake-reviews-hitting-chinese-retailers#xj4y7vzkg; *see also* https://www.wsj.com/articles/how-scammers-in-china-manipulate-amazon-11545044402.

"Contact Us" page with their respective address. Elvie included copies of its patents in the letter. *See id.*

97. In response to Elvie's letter, the entities informed Elvie that "Shenzhen TPH Technology Co., Ltd." was the alleged manufacturer of the Accused Products and that the entity "had warranted and guaranteed that it has complete intellectual property rights for those products, which do not infringe any intellectual property rights of others, including the '893 patent." *See* Dkt. #29 at 170. Momcozy continued to sell its Accused Products.

2. The APEX Proceeding

98. Elvie sought relief from Amazon itself and, on January 30, 2023, Elvie received notice that its request to participate in the Amazon APEX proceeding as to Momcozy's S12 and S12 Pro devices infringing the '893 patent had been accepted. *See* Dkt. #29, Ex. 20.

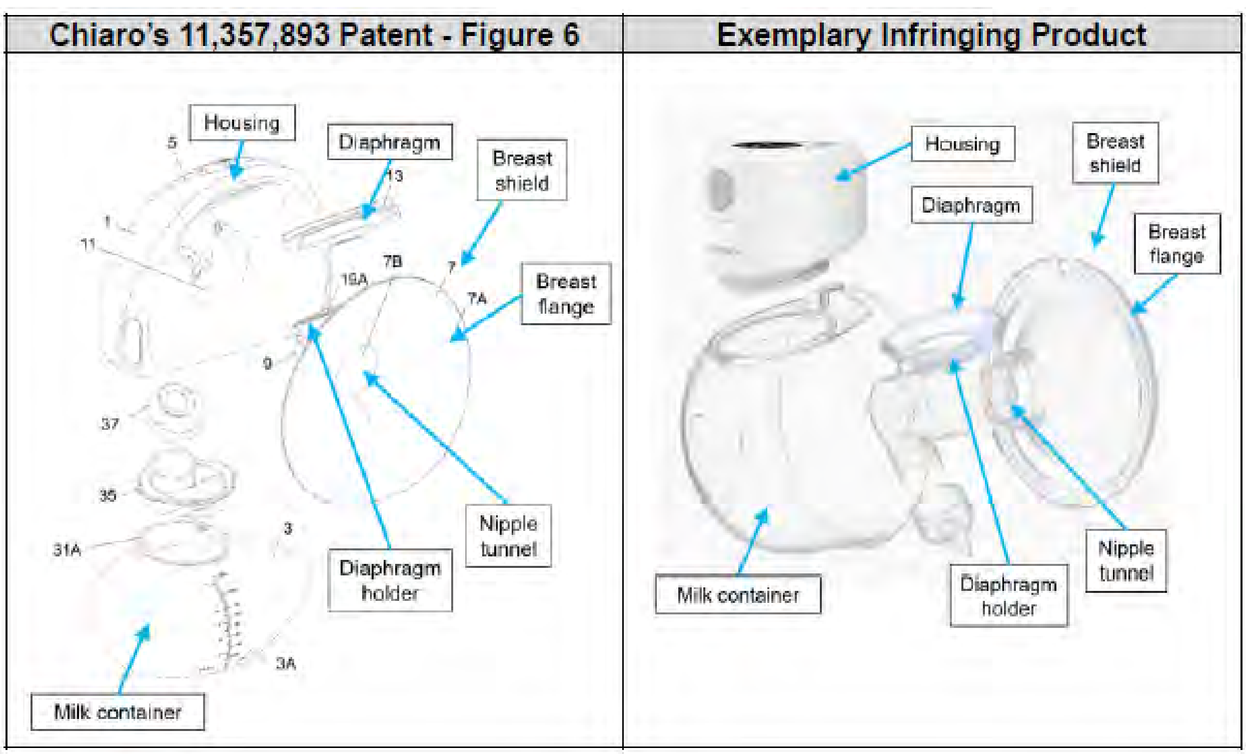
99. Two different entities responded as the "Seller" on behalf of Momcozy, "Smartlin" and "Jinruixingkeji," and agreed to participate in the APEX proceeding. *See* Dkt. #53-7; Dkt. #53-8. The person signing on behalf of the Seller was Tao Jin. *See* Dkt. #53-7. Gong Shaocong likewise signed on behalf of Smartlin. Dkt. #53-8.

100. As a part of the APEX proceeding, each party had to sign an Agreement (the "APEX Agreement") detailing the procedure of the APEX proceeding. *See* Dkt. #53-7 at 1. Specifically, the APEX Agreement notes that, "Participants agree not to disclose to third parties information or documents learned from other participants, Amazon, or Evaluator in the Evaluation, except to their respective affiliates, legal counsel or as required by law." *See id.* § 2.

101. Amazon designed its APEX procedure "[t]o efficiently resolve claims that third-party product listings infringe utility patents." Dkt. #20-5 at 1. "APEX is voluntary, confidential, and allows owners of U.S. utility patents or their authorized representatives, such as attorneys or exclusive licensees . . . to obtain a fast evaluation of patent infringement claims against products . . . , identified by Amazon Standard Identification Number, listed by third-party sellers . . . on amazon.com." *Id.*

102. If sellers volunteer to participate, a Neutral Patent Evaluator reviews a patent infringement claim against the seller's product listings on Amazon.com. *Id*. The Evaluator will set a schedule for submission of written arguments. *Id*. In general, the Schedule will provide: (i) the Patent Owner with 14 days for its initial arguments; (ii) Sellers with 14 days to respond; and (iii) the Patent Owner with 7 days to reply. *Id*. The Patent Owner may use a total of 20 double-spaced 8.5 x 11" pages between its two submissions. *Id*. Each Seller may use 15 double-spaced pages in its response. *Id*. Claim charts and exhibits are not counted against page limits. *Id*. "To make the Evaluation fast, efficient, and relatively low-cost, it is limited to one claim from one unexpired U.S. utility patent." *Id*. There are no depositions, document requests, or other forms of discovery. *Id*. The evaluator will make a yes/no decision about whether the patent covers the product listings." *Id*.

103. An experienced, partner-level patent attorney at a Boston law firm was assigned as the Neutral Patent Evaluator ("NPE") and the parties each submitted their briefing to the NPE. Elvie submitted its opening brief on March 20, 2023. *See* Dkt. #20, Ex. 6. In its opening brief, Elvie provided detailed allegations of infringement with respect to the Momcozy products at issue, including the image provided below comparing Momcozy's S12 product with the '893 patent. *See* Dkt. #20, Ex. 6 at 3.



104. Two weeks later, the entities appearing on behalf of Momcozy submitted identical responsive briefs. The parties were allowed unlimited pages for exhibits and non-infringement charts. Notably, these responsive briefs contained the same non-infringement arguments the Plaintiffs are alleging in this case.

105. One week later, Elvie submitted its reply brief.

106. After a 7-week briefing schedule, the NPE found that Elvie had shown a likelihood of success of showing infringement despite the same non-infringement arguments Plaintiffs continue to allege. Amazon removed the infringing Momcozy Amazon listings from the marketplace the next day on April 25, 2023. *See* Dkt # 1 at 9.

107. Despite the NPE's finding that Elvie demonstrated a likelihood of success of showing infringement and Amazon subsequently removing the product listings, Momcozy decided to relist its S12 Pro product back on Amazon.

3. The Declaratory Judgment Action

108. Despite the NPE informing Counterclaim Defendants that the S12 and S12 Pro products are likely to infringe claim 1 of the '893 patent, Counterclaim Defendants continue to make, use, sell, and offer for sale those products at least on its website.

109. On information and belief, Counterclaim Defendants did not and have not informed Walmart or any other reseller of the Momcozy S12 and S12 Pro of the NPE's determination regarding infringement.

110. Instead, on April 28, 2023, Plaintiffs filed a Declaratory Judgment Action against Elvie seeking a declaratory judgment that its S12 and S12 Pro devices do not infringe the '893 patent. *See generally* Dkt. #1.

111. By the time Plaintiffs filed their Declaratory Judgment Action, Elvie had interacted with no less than seven different entities claiming to be Momcozy.

112. Despite signing the APEX Agreement, which contained a confidentiality clause, Plaintiffs publicly used documents and information they received through the APEX Proceeding

to support their Complaint, including a detailed discussion of Elvie's infringement arguments in the APEX Proceeding. *See* Dkt. #1, ¶ 20.

113. Plaintiffs then filed for a Temporary Restraining Order ("TRO") claiming immediate harm despite their extensive delay in seeking a TRO. *See* Dkt. #17. Again, Plaintiffs publicly used information considered confidential under the APEX Agreement to support its claims. *See, e.g. id.* at 12; *see also* Dkt. #20, Ex. 6; Dkt. #22, Exs. 10–11, 15–16.

114. In its Opposition to Plaintiffs' TRO, Elvie pointed out that it had never heard of the then sole Plaintiff entity, Shenzhen Root Technology Co., Ltd., or Pan Silin. *See* Dkt. #28 at 9–10. Rather, the only Momcozy-related entities Elvie was aware of were (1) the recipients of Elvie's cease-and-desist correspondence ("Shenzhen Root E-Commerce Co., Ltd." and "Hong Kong Dian Ying Industry Co. Ltd." *See id.* at 10; *see also id.* Ex. 18); (2) Shenzhen TPH Technology Co., Ltd., the entity Shenzhen Root E-Commerce Co., Ltd. and Hong Kong Dian Ying Industry Co. Ltd. pointed out to Elvie as the manufacturer of the S12 product (*see id.* Ex. 17); and (3) the participants in the APEX proceeding ("Smartlin" and "Jinruixingkeji").

115. In response, Pan Silin submitted a declaration stating that "Shenzhen Root Technology Co., Ltd." is the same entity as "Shenzhen Root E-Commerce Co., Ltd." *See* Dkt. #39, ¶ 2.

116. However, public records show that Shenzhen Root Technology Co., Ltd. and Shenzhen Root E-Commerce Co., Ltd. are not the same entities.

117. Rather, Shenzhen Root Technology Co. has a USCC of 91440300MA5FX6EH4G while Shenzhen Root E-Commerce Co., Ltd. has a USCC of 91440300359646166T. *Compare* Dkt. #35-1 at 5, Dkt. #35-2 at 2, 4 *with* Dkt. #53, Ex. 4 at 8 (disclosing the latter USCC and a 2022 name change from "Shenzhen Lute (Root) E-Commerce Co. Ltd." to yet another undisclosed company "Shen Zhen Yuyou Technology Co., Ltd.").

118. Elvie has propounded discovery regarding the relationship between these entities and regarding the corporate structure of the Counterclaim Defendants.

119. Plaintiffs TRO was eventually denied. *See* Dkt. #43.

120. In the Order Denying the TRO, the Court stated that "based on its initial review of the '893 Patent, the Court tentatively believes that Plaintiff is likely to prevail on the merits" but that "the harms cited are not so immediate and irreparable that an emergency TRO is appropriate." Dkt. #43 at 7. The Order further stated that it "will further evaluate the motion at the preliminary-injunction stage with the benefit of additional briefing and a hearing." Dkt. #43 at 6–7.

121. However, Plaintiffs used the Court's TRO denial to request that Amazon relist the Accused Products. *See* Dkt. #53-1 at 2. Amazon stated that, "we are interpreting the TRO order as an order finding that the S12 Pros do not infringe." Dkt. #53-1 at 2. Amazon subsequently relisted the S12 and S12 Pro products. *See id.*

122. Because Elvie did not receive a full and fair opportunity to respond to Plaintiffs' TRO, Elvie filed a Motion for Reconsideration to clarify the Court's Order when denying the TRO. *See* Dkt. #53. There, Elvie pointed out the discrepancies in Pan Silin's declaration, including facts relating to whether the Court has jurisdiction over Plaintiff Shenzhen Root's case, as described on pages 6 and 7.

123. In response, Plaintiffs filed a new complaint adding two new plaintiffs, Hong Kong Lute Technology Co., Ltd. and Shenzhen Conglin E-Commerce Co., Ltd. *See* Dkt. #54. Once again, neither of these entities were the entities Elvie communicated with for the cease-and-desist letter or through the APEX Proceeding.

124. On May 31, 2023, Elvie filed a Motion for Reconsideration, seeking modification of the Court's Order Denying the TRO. *See* Dkt. #53. The Court denied Elvie's Motion for Reconsideration but stated in its Order that "its merits determination is—as the order states—at most 'tentative.'" *See* Dkt. #59 at 2.

125. The Court also noted regarding the jurisdiction issue that "[s]ome of the facts raised by Defendants are troubling." *See* Dkt. #59 at 3.

4. Counterclaim Defendants' Infringing Activity is Willful

126. Counterclaim Defendants' infringing conduct is willful.

127. On information and belief, Defendants sought to copy Elvie's patented products, including the Elvie Pump and Elvie Stride. Moreover, Elvie provides notice to prospective infringers of its extensive patent portfolio via its website in order to protect its hard-earned innovations. *See* https://www.elvie.com/en-us/patents. This publication satisfies the standard for constructive notice under 35 U.S.C. § 287(a) for purposes of virtual patent marking.

128. Counterclaim Defendants were on notice that the Accused Products infringed Elvie's patents since, at least, June 22, 2022, when Elvie sent Momcozy a cease-and-desist letter. *See* Dkt #1-4 at 2–3; Dkt. #29 at 170–71.

129. Despite Elvie's cease-and-desist letter, Counterclaim Defendants continued to sell the Accused Products. *See, e.g.*, Dkt. #53-1.

130. Through the APEX Proceeding, Counterclaim Defendant received detailed knowledge of how its Accused Products infringed, at least, claim 1 of the '893 patent. *See, e.g.*, Dkt. #20, Ex. 6.

131. Despite receiving this knowledge, Counterclaim Defendants continued to sell its Accused Products.

132. Through the APEX Proceeding, a neutral third-party determined that it was likely Momcozy's products infringed, at least, claim 1 of the '893 patent.

133. Despite these findings, Counterclaim Defendants continued to sell its Accused Products.

134. Instead of ceasing the sale of the Accused Products that infringed Elvie's patents, Counterclaim Defendants filed a Declaratory Judgment Action against Elvie because Amazon requires a finding of non-infringement or invalidity to continue selling on Amazon.

135. In addition, Counterclaim Defendants filed for a TRO, which was denied.

136. In its Order denying the TRO, the Court never made a finding of non-infringement or invalidity.

137. In its Order denying the TRO, the Court requested Elvie show cause of why it should not grant a preliminary injunction.

138. Before Elvie could respond with its full briefing, Counterclaim Defendants submitted the Order denying the TRO to Amazon, which Amazon then interpreted as the Court making a finding of non-infringement.

139. Amazon took the Order denying the TRO as a finding of non-infringement and relisted Counterclaim Defendant's Accused Products at Counterclaim Defendant's insistence.

140. Plaintiffs withdrew the Motion to TRO, denying Elvie the chance to fully respond to Plaintiffs allegations of non-infringement.

141. To date, the only fully briefed ruling that has been made is that the Accused Products infringe, at least, claim 1 of the '893 patent.

142. Despite this, Counterclaim Defendants continue to sell the Accused Products.

143. Counterclaim Defendants' willful conduct began, at least, as of the date of Elvie's cease-and-desist letter. The willful conduct was only compounded when it received the NPE's determination that the Accused Products likely infringed the '893 patent.

144. Counterclaim Defendants' willful conduct continued on when it received the TRO denial and used that denial to ask Amazon to re-list its Accused Products on Amazon despite knowing it had not yet received a finding of non-infringement.

145. Counterclaim Defendants should be deemed to willfully infringe the Asserted Patents, at least, as of June 2022 or the date of issuance, whichever is earlier.

146. In addition, on information and belief, Counterclaim Defendants' marketing mimics that of Elvie's. For example, the following S12 advertisement that began running on September 26, 2023 copies the imagery of Elvie's long-running advertisement of the Elvie Pump available on at least Elvie's Amazon page:

147. Further, Counterclaim Defendants' V1 and V2 products are nearly identical to Elvie's Stride product that is covered by the '454 patent. Elvie's patents, including those covering the Elvie Stride, are listed on Elvie's website. *See, e.g.*, https://www.elvie.com/en-us/patents.

148. Counterclaim Defendants' knowledge of the Asserted Patents and the Accused Products' infringement thereof is sufficient to satisfy the knowledge element for induced, contributory, and willful infringement.

149. Elvie is entitled to trebled damages for Counterclaim Defendants' willful infringement.

Count I

(Infringement of U.S. Patent No. 11,357,893)

150. The allegations of paragraphs 1 through 149 are realleged and reincorporated by reference as if fully set forth herein.

151. The ’893 patent is directed towards a wearable breast pump system including a housing shaped at least in part to fit inside a bra and an air-pump. Exemplary claim 1 of the ’893 patent recites:

> A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device containing:
> a housing that includes:
> a battery, and
> a pump powered by the battery and generating negative air pressure;
> a breast shield made up of a breast flange and a nipple tunnel;
> a milk container that is configured to be attached to and removed from the housing; and
> a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing, the diaphragm deforming in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

152. Counterclaim Defendants have directly infringed and continue to directly infringe one or more claims of the ’893 patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing into the United States products that include, but are not limited to, the S9, S9 Pro, S12, S12 Pro, M1, and M5 devices. For example, Counterclaim Defendants’ Accused Products include or perform each and every limitation of at least, claim 1 of the ’893 patent, either literally or under the doctrine of equivalents.

153. Elvie attaches hereto Exhibits 10-15 which provide exemplary claim charts describing how the Accused Products meet the limitations described in claim 1 of the ’893 patent.

154. Counterclaim Defendants also indirectly infringe one or more claims of the Asserted Patents in violation of 35 U.S.C. § 271(b) and/or (c) by actively inducing infringement of the Asserted Patents by other by offering to sell or selling within the United States a device covered by the claims of the Asserted Patents that is not a staple article or commodity of the commerce suitable for substantial non-infringing uses.

155. For example, Counterclaim Defendants instruct customers of their Accused Products on how to use and operate the Accused Products.

156. Counterclaim Defendants' direct and indirect infringement of the '893 patent has been, and continues to be, willful. On information and belief, Plaintiffs have been aware of the '893 patent since before the filing of this Complaint and has infringed the '893 patent willfully and deliberately and with knowledge that such conduct violates 35 U.S.C. § 271.

157. Counterclaim Defendants' infringement of the '893 patent has damaged, and continues to damage Elvie in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Elvie would have made but for Momcozy's infringing acts as provided by 35 U.S.C. § 284.

158. Elvie will suffer irreparable harm unless Plaintiffs are enjoined from infringing the '893 patent.

Count II

(Infringement of U.S. Patent No. 11,413,380)

159. The allegations of paragraphs 1 through 158 are realleged and reincorporated by reference as if fully set forth herein.

160. The '380 patent is directed towards a wearable breast pump system including a housing shaped at least in part to fit inside a bra and an air-pump. Exemplary claim 29 of the '380 patent recites:

> A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:
> a self-contained, in-bra wearable device comprising:
> a housing that includes:
> a rechargeable battery,
> a power charging circuit for controlling charging of the rechargeable battery,
> control electronics powered by the rechargeable battery,
> a pump powered by the rechargeable battery and configured to generate negative air pressure, and
> a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery;
> a breast shield made up of a breast flange and a nipple tunnel;
> a milk container that is configured to be attached to and removed from the housing; and
> a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing, the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

161. Counterclaim Defendants have directly infringed and continue to directly infringe one or more claims of the ’380 patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing into the United States products that include, but are not limited to, the S9, S9 Pro, S12, S12 Pro, M1, and M5 devices. For example, Counterclaim Defendants’ Accused Products include or perform each and every limitation of at least, claim 29 of the ’380 patent, either literally or under the doctrine of equivalents.

162. Elvie attaches hereto Exhibits 16–21 which provide exemplary claim charts describing how the Accused Products meet the limitations described in claim 29 of the ’380 patent.

163. Counterclaim Defendants also indirectly infringe one or more claims of the ’380 patent in violation of 35 U.S.C. § 271(b) and/or (c) by actively inducing infringement of the ’380 patent by offering to sell or selling within the United States a device covered by the claims of the ’380 patent that is not a staple article or commodity of the commerce suitable for substantial non-infringing uses.

164. For example, Counterclaim Defendants instruct customers of their Accused Products on how to use and operate the Accused Products.

165. Counterclaim Defendants’ direct and indirect infringement of the ’380 patent has been, and continues to be, willful. On information and belief, Counterclaim Defendants have been aware of the ’380 patent since before the filing of this Complaint and has infringed the ’380 patent willfully and deliberately and with knowledge that such conduct violates 35 U.S.C. § 271.

166. Counterclaim Defendants’ infringement of the ’380 patent has damaged, and continues to damage, Elvie in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Elvie would have made but for Counterclaim Defendants’ infringing acts as provided by 35 U.S.C. § 284.

167. Elvie will suffer irreparable harm unless Counterclaim Defendants are enjoined from infringing the ’380 patent.

<u>Count III</u>

(Infringement of U.S. Patent No. 11,813,381)

168. The allegations of paragraphs 1 through 167 are realleged and reincorporated by reference as if fully set forth herein.

169. The ’381 patent is directed towards a wearable breast pump system including a housing shaped at least in part to fit inside a bra and an air-pump. Exemplary claim 1 of the ’381 patent recites:

> A breast pump device comprising:
> a self-contained, in-bra wearable device comprising:
> a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge;
> a housing that includes:
> a battery, and
> the air pump powered by the battery and configured to generate negative air pressure by driving the diaphragm;
> a breast shield comprising a breast flange and a nipple tunnel extending from the breast flange, the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and the breast shield being separate from the diaphragm; and;
> a milk container that is configured to attach to the housing and receive expressed milk via the milk port.

170. Counterclaim Defendants have directly infringed and continue to directly infringe one or more claims of the ’381 patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing into the United States products that include, but are not limited to, the S9, S9 Pro, S12, and S12 Pro. For example, Counterclaim Defendants’ Accused Products include or perform each and every limitation of at least, claim 1 of the ’381 patent, either literally or under the doctrine of equivalents.

171. Elvie attaches hereto Exhibits 27-30 which provide exemplary claim charts describing how the Accused Products meet the limitations described in claim 1 of the ’381 patent.

172. Counterclaim Defendants also indirectly infringe one or more claims of the Asserted Patents in violation of 35 U.S.C. § 271(b) and/or (c) by actively inducing infringement of the Asserted Patents by others by offering to sell or selling within the United States a device

covered by the claims of the Asserted Patents that is not a staple article or commodity of the commerce suitable for substantial non-infringing uses.

173. For example, Counterclaim Defendants instruct customers of their Accused Products on how to use and operate the Accused Products.

174. Counterclaim Defendants' direct and indirect infringement of the '381 patent has been, and continues to be, willful. On information and belief, Plaintiffs have been aware of the '381 patent since its issuance date and has infringed the '381 patent willfully and deliberately and with knowledge that such conduct violates 35 U.S.C. § 271.

175. Counterclaim Defendants' infringement of the '381 patent has damaged, and continues to damage Elvie in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that Elvie would have made but for Momcozy's infringing acts as provided by 35 U.S.C. § 284.

176. Elvie will suffer irreparable harm unless Counterclaim Defendants are enjoined from infringing the '381 patent.

Count IV

(Infringement of U.S. Patent No. 11,806,454)

177. The allegations of paragraphs 1 through 176 are realleged and reincorporated by reference as if fully set forth herein.

178. The '454 patent is directed towards a wearable breast pump system including a housing shaped at least in part to fit inside a bra and an air-pump. Exemplary claim 17 of the '454 patent recites:

> A breast pump system comprising:
> a control unit comprising:
> a battery, and
> a pump configured to be powered by the battery and to generate negative air pressure; and
> a wearable milk collection hub configured to connect to the control unit via an air line, the wearable milk collection hub comprising:
> a breast shield comprising:
> a breast flange; and
> a nipple tunnel extending from the breast flange;

a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel;

an outer shell comprising a rear end configured to removably attach to the breast shield and, an interior volume between the outer shell and the breast shield defining a chamber to receive expressed milk; and

a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell, the front end being opposite to the rear end, the diaphragm cap forms a central region on a front surface of the outer shell.

179. Counterclaim Defendants have directly infringed and continue to directly infringe one or more claims of the ’454 patent in violation of 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing into the United States products that include, but are not limited to, the V1 and V2. For example, Counterclaim Defendants’ V1 and V2 include or perform each and every limitation of at least, claim 17 of the ’454 patent, either literally or under the doctrine of equivalents.

180. Elvie attaches hereto Exhibits 31-32 which provide exemplary claim charts describing how the V1 and V2 products meet the limitations described in claim 17 of the ’454 patent.

181. Counterclaim Defendants also indirectly infringe one or more claims of the Asserted Patents in violation of 35 U.S.C. § 271(b) and/or (c) by actively inducing infringement of the Asserted Patents by others by offering to sell or selling within the United States a device covered by the claims of the Asserted Patents that is not a staple article or commodity of the commerce suitable for substantial non-infringing uses.

182. For example, Counterclaim Defendants instruct customers of their V1 and V2 products on how to use and operate the V1 and V2 products.

183. Counterclaim Defendants’ direct and indirect infringement of the ’454 patent has been, and continues to be, willful. On information and belief, Plaintiffs have been aware of the ’454 patent since its issuance date and has infringed the ’454 patent willfully and deliberately and with knowledge that such conduct violates 35 U.S.C. § 271.

184. Counterclaim Defendants’ infringement of the ’454 patent has damaged, and continues to damage Elvie in an amount yet to be determined, of at least a reasonable royalty

and/or lost profits that Elvie would have made but for Momcozy's infringing acts as provided by 35 U.S.C. § 284.

185. Elvie will suffer irreparable harm unless Counterclaim Defendants are enjoined from infringing the '454 patent.

Count V

(Breach of Contract)

186. The allegations of paragraphs 1 through 185 are realleged and reincorporated by reference as if fully set forth herein.

187. The APEX Agreement is a valid, binding, and enforceable agreement between Elvie and Momcozy that was made for valid consideration, including the exchange of information intended to facilitate the APEX proceeding.

188. Elvie fully performed its contractual duties and obligations under the APEX Agreement.

189. Under the Agreement, Momcozy was prohibited from "disclos[ing] to third parties information or documents learned from" the APEX proceeding. Dkt. #53-7 § 2.

190. In the filing of its complaint, Plaintiffs publicly disclosed information and documents that it learned from the APEX proceeding, including, but not limited to, communications with Amazon. *See* Dkt. #20, Ex. 6; Dkt. #22, Exs. 10–14; Dkt. # 54, Amended Compl. ¶ 28; Dkt. #21, Motion for TRO at 2, 19–20.

191. As a result of Plaintiffs' breach of the Apex Agreement, Elvie has suffered damages in an amount to be proven at trial, including Amazon's decision to reinstate Momcozy's Accused Products on its website.

PRAYER FOR RELIEF

WHEREFORE, Defendant and Counterclaim Plaintiff Elvie requests that this Court enter judgment in favor against Counterclaim Defendants and grant to Elvie the following relief:

A. Find that Counterclaim Defendants are infringing the Asserted Patents in violation

of 35 U.S.C. § 271 (a), (b), and/or (c);

B. Enter an order preliminarily and permanently enjoining Counterclaim Defendants, their officers, directors, agents, servants, employees, and all other persons in privity or acting in concert with them who receive actual notice of the order by person serve or otherwise, from any further acts of infringement of the Asserted Patents;

C. Award Elvie damages in an amount adequate to compensate Elvie for Counterclaim Defendants' infringement of the Asserted Patents;

D. Treble any and all damages award to Elvie by reason of Defendants' willful infringement of the Asserted Patents pursuant to 35 U.S.C. § 284;

E. Award Elvie interest on damages award and their costs pursuant to 35 U.S.C. § 284;

F. Find that this is an exceptional case and awarding Elvie its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

G. Find that Counterclaim Defendants breach the APEX Agreement under Washington common law;

H. Award Elvie recoverable damages in an amount to be determined at trial, including an award of compensatory and actual damages, punitive damages, reasonable attorneys' fees, prejudgment interest, post-judgment interest, and costs; and

I. Award such other and further relief as this Court deems proper.

DEMAND FOR JURY TRIAL

Elvie respectfully requests a trial by jury of all issues properly triable by jury in action. this

Executed this ___ day of March 2024.

Lowe Graham Jones PLLC

Respectfully submitted,

Lowe Graham Jones PLLC

____
Mark P. Walters, WSBA No. 30819
Mitchell D. West, WSBA No. 53103
walters@LoweGrahamJones.com
west@LoweGrahamJones.com
1325 Fourth Avenue, Suite 1130
Seattle, WA 98101
T: 206.381.3300
F: 206.381.3301

____
Nirav N. Desai (*pro hac vice*)
Josephine Kim (*pro hac vice*)
Alexander Covington (*pro hac vice*)
Alex Alfano (*pro hac vice*)
Joseph Kim (*pro hac vice*)
Paige Cloud (pending *pro hac vice*)
Michael Webb (*pro hac vice*)
Richa Patel (*pro hac vice*)
Zachary L. Jacobs (*pro hac vice*)
Christopher Coleman (*pro hac vice*)
STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1101 K St NW, 10th Floor
Washington, DC 20005
Telephone: 202.371.2600
Facsimile: 202.371.2540

Exhibit 1

Establishment Registration & Device Listing

New Search | Back To Search Results

Proprietary Name:	Wearable Breast Pump (Model S18); Wearable Breast Pump (Model S10pro); Wearable Breast Pump (Model S19); Wearable Breast Pump (Model S21); Wearable Breast Pump (Model S23); Wearable Breast Pump (Model S28); Wearable Breast Pump (Model S9)
Classification Name:	PUMP, BREAST, POWERED
Product Code:	HGX
Device Class:	2
Regulation Number:	884.5160
Medical Specialty:	Obstetrics/Gynecology
Registered Establishment Name:	SHENZHEN TPH TECHNOLOGY CO., LTD.
Registered Establishment Number:	3016975995
Premarket Submission Number:	K220596
Owner/Operator:	Shenzhen TPH Technology Co., Ltd.
Owner/Operator Number:	10084349
Establishment Operations:	Manufacturer

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Exhibit 2

Establishment Registration & Device Listing

New Search | Back To Search Results

Proprietary Name:	S10 Wearable Breast Pump; Wearable Breast Pump (Model S12); Wearable Breast Pump (Model S13); Wearable Breast Pump (Model S22); Wearable Breast Pump (Model S32); Wearable Breast Pump(Model S39)
Classification Name:	PUMP, BREAST, POWERED
Product Code:	HGX
Device Class:	2
Regulation Number:	884.5160
Medical Specialty:	Obstetrics/Gynecology
Registered Establishment Name:	SHENZHEN TPH TECHNOLOGY CO., LTD.
Registered Establishment Number:	3016975995
Premarket Submission Number:	K212180
Owner/Operator:	Shenzhen TPH Technology Co., Ltd.
Owner/Operator Number:	10084349
Establishment Operations:	Manufacturer

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Exhibit 3

1by1

Achievements at Elvie + Chiaro

Published on March 25th, 2023

We created some brilliant products at Elvie, between 2014 and 2022. They were truly innovative, game changing products. They not only led to the creation of new product categories, and a whole host of competitors following us, but the company was instrumental in changing the conversation around taboo areas of women's health. We led the charge in the FemTech revolution, and have definitely had a lasting impact that has gone far wider than just the connected devices that we invented, designed, manufactured and brought to market.

Here's a selection of the awards, prizes and recognition we received for the work we did - these are the result of a great team working hard to deliver on a great mission:

Elvie Trainer

- Best R&D product - AXA PPP Health Tech and You 2015
- **Product Design Award - Red Dot Awards 2016**
- Best Exercise Product (Silver) - Mumii Family Awards 2017
- Best Gadget (Gold) - Mumii Family Awards 2017

- Postnatal Health and Well Being (Bronze) - Best Baby & Toddler Gear Awards 2017
- Body Recovery Products Top Choice of the Year - babyMaternity Magazine Awards 2017
- HealthTechXEurope Award Winner 2017
- **Winner Women's Health FemTech Award 2018**
- Winner Best Sexual Wellness Aid in Glamour UK's Wellness Power List Awards 2021

Elvie Pump

- Elvie Pump IoT Wearable Device of the Year Marquee award - IoT Breakthrough 2018
- **TIME Magazine 100 Best Inventions 2019**
- Winner of BabyList Best of Tech CES Award 2019
- **Winner Dezeen Awards Wearable Design of the Year 2019**
- Winner of Children Products Health and Baby Care Category - International Design Award 2019
- Winner Women's Health Editors Choice Best of CES Award 2019
- Winner BestProducts.com Best of CES Award 2019
- Winner Healthcare Wearable solutions - IOT/WT Innovation World Cup 2019
- Winner Mumsnet Best Discreet Pump 2019
- Winner Mom's Choice Award Personal Use Products 2019
- Winner Parent & Baby Awards as most innovative wearable breast pump 2019
- Winner Baby Magazine Best New Product 2019
- Winner Popular Science Best of What's New Award in Personal Health 2019
- **Product Design Award - Red Dot Awards 2020**
- Winner The Red Dot: Best of the Best award 2020

- Winner The Red Dot: Innovative Products category 2020
- Winner Good Design Awards 2020
- Winner Best Breast Pump in Mother & Baby Awards 2020
- Winner Best Product in the judges' categories in The Baby Awards 2020
- Winner Best Breast Pump, Hip and Healthy Wellness Awards 2021
- Gold Award, Wearable Electric Breast Pump category, Made For Mums Awards 2022
- Gold Award in the 'Game-Changer Product' category, Made For Mums Awards 2022

Elvie Stride

- **TIME Magazine 100 Best Inventions 2021**
- **Product Design Award - Red Dot Awards 2022**

Elvie

- Best Startup Business - Wearable Technology Show 2015
- Hottest Tech Startup of the Year - The Smart Tech Show 2017
- Hottest Hardware Startup - The Europas 2017
- 'One to Watch' - Sunday Times Hiscox Tech Track 100 2017
- 13th fastest-growing business in the UK - Top 100: Britain's Fastest-growing Businesses Report by Syndicate Room 2018
- 100 Hottest Startups - Wired Magazine 2018
- Venture Funded Business of the Year Award at Startups Awards 2018
- #32 Deloitte Fast 50 2019
- #76 in FT1000 - Europe's Fastest Growing Companies 2020, and #2 in Healthcare 2020
- #3 in FastCo's most innovative company in the Europe category 2020
- #7 in The Sunday Times Sage Tech Track 100 - fastest growing companies in the UK 2020

- #41 in the FT 1000 list of fastest growing companies in Europe 2021
- #26 fastest-growing private tech company in UK, Deloitte Fast 50 2021
- #75 in the FT 1000 Europe's Fastest Growing Companies 2022

Exhibit 4

A More Subtle Breast Pump

Elvie Breast Pump

Joe Lingeman for TIME

Two years ago, a portable, wearable breast pump appeared on TIME's Best Inventions list as an alternative to heavy, noisy pumping machines. Since then, more have come to market, including Elvie, which has emerged as a leader in the field. Elvie has no tubes or wires, and uses a nearly silent motor. It is lighter, slimmer and quieter than competitors, allowing moms to discreetly pump while performing daily activities. A set costs $499, or moms can opt for one pump for $279. —*Emily Barone*

Buy now: Elvie Breast Pump

Exhibit 5

Runner Up
Health & Wellness Award
Core77 Design Awards 20

Results Announced for Community Choice Prize

See All Winners

Elvie

HONOREE

Chiaro Technology

Elvie Pump is the world's first silent wearable breast pump. Elvie Pump is a complete

departure from existing pump technology, creating an entirely new pumping experience that offers more freedom and mobility. The truly hands-free pump gives women the flexibility to go about their daily routine while pumping, without worrying about cords, wardrobe changes or the undignified sound of traditional electric breast pumps.

Elvie's proprietary pump technology means the pump is the quietest, smallest and most lightweight wearable breast pump on the market. Worn under clothing, Elvie Pump offers unprecedented discretion when pumping collecting milk in its self-contained bottle. Women can view real-time milk volume and track their pumping history for each breast.

Elvie Pump uses infrared technology to detect the amount of milk in the bottle, enabling it to identify when the bottle is full and automatically end the pumping session. Users can control the pump from their smartphone, avoiding the need to open your blouse and fiddle with buttons, allowing pumping in more locations than ever possible before.

Elvie Pump enables and encourages more women to breastfeed for the benefit of both the baby and the mother's health. It also helps to relieve the symptoms of mastitis and allows more sessions in a mother's day which results in an increase in milk supply.

CLIENT

Chiaro Technology

CATEGORY

Health & Wellness

VIEW MORE INFORMATION

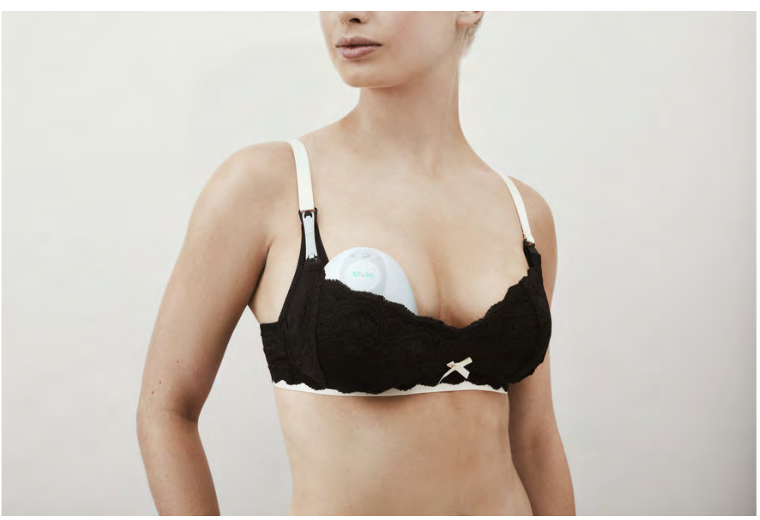
Website


elvie


elvie
140


elvie


elvie



0:00 / 1:18

There have been over 200 expressing women involved in the development of Elvie Pump. From product conception through to the final prototype builds, we've been listening and implementing their insights, giving us absolute confidence that this is what women want.

Our unique technology and design mean that there are many more differences when it comes to ease of assembly and cleaning, as well as charging, durability and app features that we think moms will immediately value. By placing women at the center of the design process we've been able to create a product

that makes pumping as easy, convenient and comfortable as possible.

One of the first things that comes up in conversation with women who have experienced pumping is the noise. These conversations usually start with a few impressions of the loud, mechanical sounds that ultimately left many women feeling totally dehumanized. It was apparent that this needed to be eliminated, and it became an absolute necessity in the design process.

The cords, tubes and bulky kit were another aspects that made for an undesirable experience, and by their look, seemed to be stuck in a previous century. The innovative technology used in Elvie Pump allows it to be lightweight and small in size. The washable components are designed so that they fit together to form an ergonomic shape, meaning that Elvie Pump can easily fit into a standard nursing bra. To accommodate all bra types, as some have stretch and others less so, each Elvie Pump is provided with a Bra Adjuster so that there is always the option to extend the cup size if needed.

There are only 5 washable parts so that, as well as being easy to clean, Elvie Pump can be put together in seconds. Each pump can be either left or right breast and easily switched over in either the app or the Hub. When single pumping, the Side Selector makes it easy to

switch sides, restarting in Stimulation mode if pressed during a session.

Elvie Pump can be controlled via the app to avoid having to fiddle underneath clothes whilst pumping, keeping the entire experience discreet from start to finish. The app also gives real-time feedback as to how much milk is in the bottle so the woman using it always knows what's going on. Elvie Pump automatically switches off when the bottle is full, allowing the user to concentrate on other things.

An important but often overlooked or ambiguous aspect of pumping is flange / breast shield sizing. Getting the correct fit is essential for comfort and performance. Elvie Pump's breast shields have a unique sizing system placed on the underside of the breast shield that allows the user to determine the best fit for her.

It was important that this pump fits into women's lives, rather than altering it. So, Elvie Pump was designed as a product that women would want to interact with, rather than begrudge every moment they spend with it.

The future of breast pumps is wearable, and the products on the shelves will look dramatically different within the next two years. Women need a breast pump that is designed for their modern lives and being mobile is a huge part of that. There has never been a truly hands-free, silent and smart breast pump before Elvie Pump. This is the

'iPhone moment' for the category and will completely transform the pumping experience for new moms.

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Core77 Design Awards 2019

Built Environment
Commercial
Equipment
Consumer
Technology
Crowdfunding
Design Education
Initiative

Design for Social
Impact
Furniture & Lighting
Health & Wellness
Home & Living
Interaction
Packaging
Personal Accessory

Service Design
Speculative Design
Sports & Recreation
Strategy & Research
Tools & Work
Transportation
Visual
Communication

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Exhibit 6

in partnership with BENTLEY dezeen awards 2023

2019 results

Winners | Shortlists | Judges

All | Architecture | Interiors | Design | Studios

Design project of the year | Furniture design | Seating design | Lighting design | Homeware design | Workplace design | Wearable design | Product design | Sustainable design | Graphic design | Installation design

Elvie Pump
by Elvie

Winner of wearable design of the year at Dezeen Awards 2019, the Elvie Pump is the world's first silent wearable breast pump from technology company Elvie.

Designed to be worn inconspicuously in any nursing bra, Elvie's breast pump is intended to be a complete departure from existing pump technology. Putting women at the centre of the design

Unlike most devices for expressing milk, the pump is compact and wire-free, so new mothers can move around freely without having to sit by a power socket or worrying about cords.

Users can also control the pump from their phone via an app.

Judges comments: "The Elvie Pump is an innovative product that addresses how society treats breastfeeding women – in the workplace, in public etc. It's a new and interesting solution that empowers women. The silent, wireless technology allows women to breastfeed on the move, using new technology to approach something so natural."

Designer: Elvie
Project: Elvie Pump
Winner of: Wearable design

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ADF
Aoyama Design Forum

有方
POSITION

DESIGNWIRE
设计腕儿

v2com
newswire

全球设计奖项研究所
Global Design Awards Lab

TOPYS. ARCHITECTUREAU

ACGMEDIA

Exhibit 7

Good Design Awards

Tell a friend

ARCHIVE 2020
Personal

GOOD DESIGN

BACK TO ARCHIVE

Elvie Pump 2019

Designers: Jonathan O'Toole, Elvie Design Team, Elvie, London, United Kingdom
Manufacturers: Chiaro Technology Ltd. and Elvie, London, United Kingdom

Elvie Pump is the world's first silent wearable breast pump; a complete departure from existing pump technology, Elvie has put women at the center of the design process to create an entirely new pumping experience that offers freedom and mobility.

The truly hands-free pump gives women the flexibility to go about their daily routine while pumping without worrying about cords, wardrobe changes, or the undignified sound of traditional electric breast pumps.

Worn in-bra discreetly, Elvie Pump gives

NEXT/PREVIOUS

The European Centre for
Architecture Art Design
and Urban Studies

28 Butlers Court
Sir Rogerson's Quay
Dubln 2, Ireland
TEL/FAX: +353/(0)1-670 8781
Email: info@europeanarch.eu

The European Centre for
Architecture Art Design
and Urban Studies / Contemporary
Space Athens

Mitropoleos 74, GR 10563
Athens, Greece
TEL: +30 210 3428511
FAX: +30 210 3428512
Email: info@europeanarch.eu

Green Good Design Awards

Europe 40 under 40

International Architecture Awards

Good Design Awards

European Prize for Architecture

Exhibit 8

FORBES VETTED

The Best Breast Pumps, According To Moms Who Have Tried Them

Korin Miller Contributor
Forbes Vetted Contributor Group

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Sep 8, 2022, 11:17am EDT

Choosing the best breast pump for your breastfeeding journey can make each pumping session a little bit easier—more successful, too. Whether you're pumping during the workday or in the wee hours of the morning, it's important to find one that fits your lifestyle, although there are some features (for instance, ease of use and adjustable suction) most moms generally need. I've been breastfeeding on and off for about a decade and am currently nursing my fourth child, so I know a thing or two about breast pumps. After trying out several options, tapping lactation consultants and asking Forbes moms for their recommendations, I assembled this list. Our top overall pick is the Spectra S1 Plus, a Forbes staffer favorite, while the powerful and affordable Medela Pump In Style is my personal top choice.

Our favorite breast pump, the Spectra S1 Plus, is powerful and easy to use. TARGET

In general, a "double electric pump is the best fit for most families," says certified lactation education counselor Rebekah Huppert, R.N., B.S.N., a lactation consultant at the Mayo Clinic. But at the end of the day, "it is important to remember that everyone responds differently to different pumps. There is no one size fits all," says Leigh Anne O'Connor, board-certified lactation consultant and La Leche League leader.

Here, you'll find the best breast pumps according to moms who have used them. Also, be sure to read about our favorite nursing and pumping bras, baby bottles and high chairs to cover more baby feeding needs.

- **Best Breast Pump Overall:** Spectra S1 Plus
- **Most Versatile Breast Pump**: Medela Pump In Style With Max Flow
- **Best Portable Breast Pump**: Medela Freestyle Flex

- **Best Wearable Breast Pump:** Elvie Double Electric
- **Best Affordable Breast Pump:** Lansinoh Smartpump 2.0
- **Best Double Motor Breast Pump:** Spectra Synergy Gold
- **Best Manual Breast Pump:** Haakaa

Best Breast Pump Overall

A Breast Pump That's Recommended Again And Again

TARGET

Spectra S1 Plus Electric Breast Pump

$216

Buy From Target

When asked their top breast pump recommendation, parents in our Forbes Moms chat group, as well as many parents in outside forums, praised the Spectra S1 Plus. A big selling point of this machine is that it's cordless, one of the main differences between it and its sister model, the S2—which we also recommend if the cordless feature isn't important to you. At around at 3.3 pounds, the S1 is still a bit cumbersome to carry, but you won't be tethered to the wall. Plus you'll avoid the hassle of a cord getting tangled with the pump tubes (and everything else).

Practicality-wise, the S1 offers both single and double pumping, has a massage mode for stimulating letdown, adjustable suction and a built-in night light—a small but helpful feature for late night feedings. Shares one Forbes mom, “It has a built-in timer, which helped during the work day, and it was as effective as a hospital grade pump.” Another adds that it’s quiet enough to pump during Zoom meetings without too much interruption.

Pros:

- Quiet
- Cordless and rechargeable
- Built-in night light

Cons:

- Cumbersome to carry around at 3.3 pounds

Most Versatile Breast Pump

A Powerful Pump With A Battery Option And Carrying Case

AMAZON

Medela Pump In Style With MaxFlow

$192 ~~$250~~ **SAVE $58 (23%)**

AT AMAZON

$192 At Amazon

$215 At Target

$260 At Best Buy

The Medela Maxflow is a popular breast pump that efficiently gets the job done. This pump features MaxFlow technology that's

inspired by hospital-grade pumps to deliver some serious suction power. You may need to dial back on the power at first—it gets to work ASAP and doesn't hold back, although it does go through a two-phase expression technology to mimic your baby's natural sucking rhythm.

The Pump In Style doesn't have a lot of parts to keep track of, which is a perk. There's just the pump itself, breast shields, bottles and tubing—and it all easily stores in a petite bag you can stash in your go-to tote for daily travel. Choose between two sizes of the brand's PersonalFit Flex breast shields to find one that most comfortably covers your size nipples. There's also a battery pack and included cooler for pumping on the go. If you're having trouble getting enough milk expressed, or if you're dealing with a lower-than-desired flow, this pump and its intense power is sure to help you max out your breastfeeding potential. It also weighs a mere pound, making it easy to tote around.

Pros:

- Strong suction
- User friendly
- Compact

Cons:

- No timer
- Can be noisy

Best Portable Breast Pump

This Tiny But Powerful Pump Weighs Less 1 Pound

MEDELA

Medela Freestyle Flex Portable Double Electric Breast Pump

$350

AT AMAZON

$350 At Amazon

$350 At Target

$396 At Babylist

At just 9.5 inches high and 13.5 inches wide and weighing in at less than 1 pound, the Medela Freestyle Flex is downright teeny compared to other pumps. It's also powered by a USB rechargeable battery, so you can seamlessly pump on the go. I took it to a wedding, and it was easy to conceal my pump in an oversized tote. My sturdy primary pump would have been obvious.

Despite its petite size, the Freestyle doesn't skimp on power: This pump can provide impressive suction, although not at the same level as hospital-grade pumps. It also features two-phase expression technology to mimic your baby's natural feeding pattern. Choose from two sizes of breast shields for that just-right fit. Once you're done, store your milk in the included cooler and toss your gear in the included carrying bag.

Pros:

- Petite and lightweight
- Powerful but quiet
- Cordless option and rechargeable

Cons:

- Less powerful than hospital grade pumps
- Battery may need to be reset after a few months

Best Wearable Breast Pump

A Cordless, Tubeless Option

MOST POPULAR

WALMART

Elvie Double Electric Breast Pump

$550 Elvie

$550 At Walmart

$550 At Target

Wearable breast pump technology is amazingly convenient, but keep in mind that these ultra-portable models aren't as powerful as hospital-grade machines. Still, if you're willing to foot the bill, they make an excellent alternative for pump sessions while you're on the

go or in the middle of a busy work day. The Elvie is one of the most popular models of its kind, earning an average review rating of around 4 stars across sites big-name sites (including Walmart).

Here's how it works: You slip the cups in your bra—you can do double or single sessions—and control the settings and track the output estimations through an app. The brand also claims this pump is silent, making it more discreet than some standard machines. The cups each have their own motor, so it's completely cordless and tubeless; just keep in mind that the battery is limited to about two and a half hours' worth of of pumping time (and it takes about two hours to recharge). Further, wearable pumping devices typically take some getting used to for the best results.

One Forbes mom admits that her traditional pump is more powerful, but "the Elvie is great on the go." Another shares, "[The] Elvie is a timesaver — Elvie is easier to assemble and manage [than a similar model]." If you want to save some cash and don't mind sacrificing a bit of convenience, consider the Elvie Stride (around $270). As opposed to the Double Electric, the Stride cups share a motor so they're connected to the pump by tubes.

Pros:

- Smart-enabled
- Completely hands-free
- Wire and cord-free

Cons:

- Limited battery (2.5 hours)
- Not as powerful as traditional breast pumps

- Pricey

Best Affordable Breast Pump

This Pump Is Powerful And Affordable

LANSINOH

Lansinoh Smartpump 2.0 Double Electric Breast Pump

$99 ~~$128~~ SAVE $29 (23%)

AT AMAZON

$99 At Amazon

$160 At Target

The Lansinoh Smartpump has a lot of features that make it easy to use—and a lower-than-average price tag to go with it. It sets up similarly to most pumps: You simply connect the tubes to the machine and bottles and get down to business. Adjust between eight suction strength levels and three pumping styles, along with hospital-grade strength to really help empty your breasts. I felt like the Smartpump got a little more out of me than my standard Medela Sonata, which is always a plus.

The Smartpump is quieter than many other pumps, so you can actually use it during work calls without having to repeatedly put yourself on mute. Conveniently, there are three power options: a plug, AA batteries or a separately purchased car adapter. A built-in carrying handle makes this pump easy to tote around, and it weighs only a pound. The whole thing is Bluetooth compatible, so you can track all the action from an app on your phone.

Pros:

- Affordable
- Strong suction but quiet
- Battery operated or plug-in

Cons:

- No rechargeable battery
- Has a lot of pieces to keep track of

Best High-End Breast Pump

A Tech-Forward Breast Pump Our Executive Editor Swears By

EDITOR'S PICK

SPECTRA

Spectra Synergy Gold Double Electric Breast Pump

$322

AT TARGET

$322 At Target

$325 At Babylist

This breast pump is on the pricier side, but reviewers, including Forbes Vetted's executive content director and new mom Cory Baldwin, swear by its powerful suction. Baldwin handpicked Spectra's latest model after getting frustrated with the subpar performance of the only option covered by her insurance (the Ameda Mya double electric breast pump). The feature that separates Spectra's Synergy Gold from other models is a double motor, which allows the user to independently select settings for each breast. (Moms can choose from among 15 vacuum suction levels on expression mode and five on massage mode.)

Spectra Synergy Gold also features a patent pending, realistic suction motion that offers "a more comfortable, and for me more productive pumping session" according to Baldwin. Other favorite features include memory settings, quiet operation, a three-level night light and an LCD touchscreen. While its sleek control panel and metallic accent may not be a necessity, it's certainly a bonus. Be aware that its dual motors make it heavy at over 5.5 pounds and it requires an outlet to operate, making it powerful but not particularly portable.

Pros:

- Independent settings for each breast
- Superior suction potential thanks to dual motor
- Memory function

Cons:

- Corded, not rechargeable
- Heavy

Best Manual Breast Pump

Soft Food-Grade Silicone Easily Suctions To Your Breast

AMAZON

Haakaa Manual Breast Pump And Cover

$22

Buy From Amazon

“Some women will do well with a manual pump,” explains certified lactation education counselor Rebekah Huppert, R.N., B.S.N. “But [manual pumps] do not work well if she is pumping with any type of consistency.” In other words, a manual pump probably won’t be the primary pump for most moms, but it’s good for short sessions or if you’re traveling and need some relief. Many women also like to use a manual pump such as the Haakaa to catch milk from the opposite breast during breastfeeding sessions.

The highly rated and ultra-affordable Haakaa is a staffer recommendation and all-around fan favorite among mom reviewers. It’s made from soft food-grade silicone that suctions to the breast and gently expresses milk, and it’s especially ideal for milk catching if you’re pumping or feeding with the other. You can get this set, which includes a leakproof lid so you can stash it right in the fridge; or, opt for the pump-only option for a mere $13. One thing to note: It’s 4-ounce capacity may be too small for a full pump session for some mamas. All in all, though, it’s a nice and affordable addition to have in your breastfeeding toolkit.

Pros:

- Affordable
- Portable
- Excellent for milk catching

Cons:

- Small 4-ounce capacity
- Works in a pinch but not for regular pumping

How We Chose The Best Breast Pumps

I've been breastfeeding on and off for about a decade and am currently nursing my fourth child. I've relied on Medela for my breast pumps since I had my oldest son in 2013. To choose our best breast pump recommendations, I looked at the top models on the market and spoke to parents and lactation consultants about which pumps they preferred. I had the opportunity to try out several other pumps over the last few weeks to compare features and to try to determine the best options for different lifestyles. I have also enlisted the help of other Forbes staffers who have experienced the breastfeeding journey; their recommendations and advice are added throughout this story.

Which Breast Pump Works Best?

If you're looking for a traditional electric breast pump from a reputable brand, the Spectra S1 Plus, Spectra Synergy Gold or Medela Pump In Style With Max Flow received top marks for effective performance overall. While some of our other picks offer perks like better portability and smart features, the aforementioned models are the most efficient at getting the job done. You could also consider renting a hospital-grade pump such as the Medela Symphony.

Can I Get A Breast Pump Through Insurance?

Yes. Most insurance companies will cover some or all of the cost of your breast pump. You can speak directly with your provider or ask your OB/GYN to guide you through options. You can also enlist the help of a third party site, such as Edgepark Breast Pumps to

simplify the process. It's worth noting that some insurance companies have restrictions around which pump you can purchase.

Does Everyone Need A Breast Pump?

"A good breast pump is a great tool to have when it is needed, but not everyone needs a pump," says Meghan Devine, R.N., B.S.N., I.B.C.L.C., clinical supervisor for the Lactation Program at Children's Hospital of Philadelphia. "If you are directly breastfeeding, your baby is growing well and you are rarely apart from each other, a pump is not necessary." But if you and your baby are unable to directly breastfeed for any reason, Devine says you'll want to have a pump. In order to build and maintain milk supply, "you will need to express your milk at least as often as your baby normally breastfeeds or a minimum of every two to three hours, eight or more times in 24 hours," Devine says.

Korin Miller

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I am a freelance writer specializing in general wellness, relationships, home, and lifestyle trends, with work appearing in Women's Health, Prevention,...

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Exhibit 9

https://www.wsj.com/articles/how-scammers-in-china-manipulate-amazon-11545044402

TECH

How Scammers in China Manipulate Amazon

This WSJ original video explains how sellers are using fake reviews, artificial sales and even bribes to deceive online consumers

By Jon Emont Follow *and Clément Bürge*

Dec. 17, 2018 6:00 am ET

Amazon users may know the feeling, especially during the holiday shopping season: Overwhelmed by choices on an e-commerce platform with more than half a billion products, many people simply decide to buy one of the best-selling items appearing at the very top of the search results.

No wonder those spots are coveted. In China and elsewhere, some Amazon sellers resort to cunning techniques to manipulate product listings, get one of those top spots, and boost their sales. There's even a cohort of self-proclaimed experts, sometimes called "gurus," who claim to have mastered the art of algorithm manipulation. They charge thousands of dollars for advice that they advertise as the key to immediate commercial success. Those shadowy tactics often breach Amazon's rules.

Aware of these violations, Amazon says it has zero tolerance for abuse of its systems and that it takes swift action against bad actors.

The Wall Street Journal investigated for months in Shenzhen, Hong Kong and San Francisco and found fake reviews, artificial sales and bribes are among the most popular methods in the "guru" toolbox. This video explains how some Chinese sellers are finding shortcuts to beat their competitors on America's largest e-commerce platform—and how you can spot sham listings.

—Laura Stevens contributed to this article.

Write to Jon Emont at jonathan.emont@wsj.com and Clément Bürge at clement.burge@wsj.com

Exhibit 10

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M1**
Claim 1		
1.1	A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:	The Momcozy M1 is a breast pump device. The Momcozy M1 is described as a “Wearable Breast Pump.” (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) The Momcozy M1 is a breast pump device that is configured as a self-contained device, as shown below. 

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

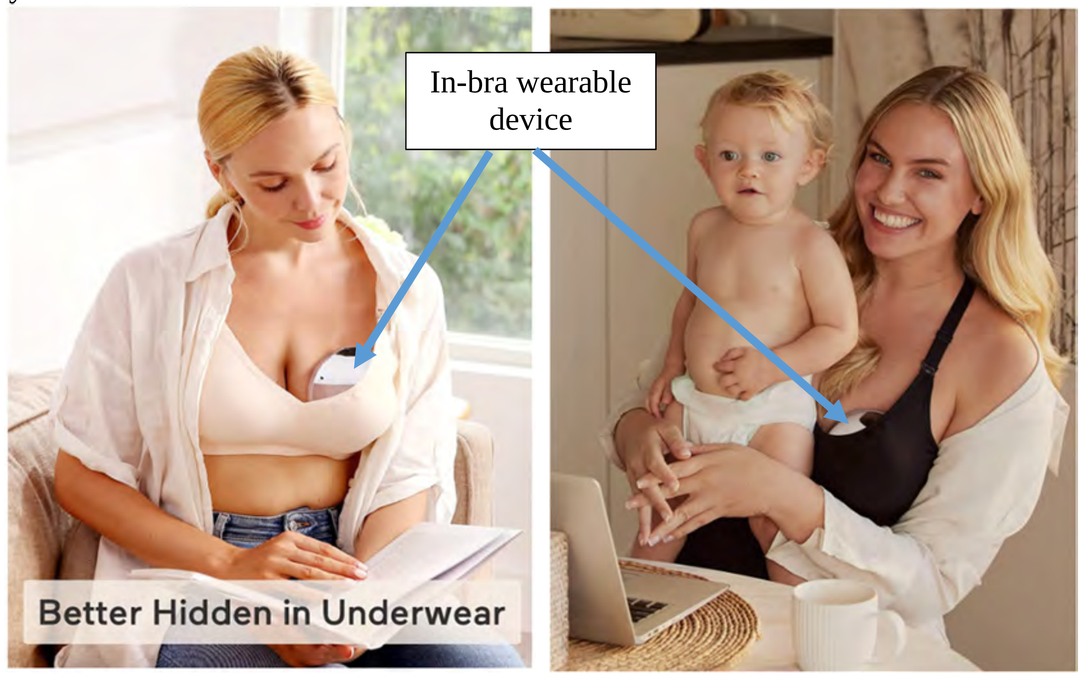
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.		
Claim Language		**Momcozy M1**
		The Momcozy M1 is an in-bra wearable device.  (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) As shown above, the Momcozy M1 fits inside a user's bra. Momcozy's Amazon listing describes the Momcozy M1 as "Momcozy Double Wearable Breast Pump M1" that is a "Portable All-in-One Breastfeeding Breast Pump." (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) Momcozy's Amazon listing indicates that the Momcozy M1 includes "All-in-one Design - Electric Breast Pump M1 is completely invisible when wearing underwear." (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) Momcozy further advertises that the "M1 is fit for nursing bras." (*Id.*)

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

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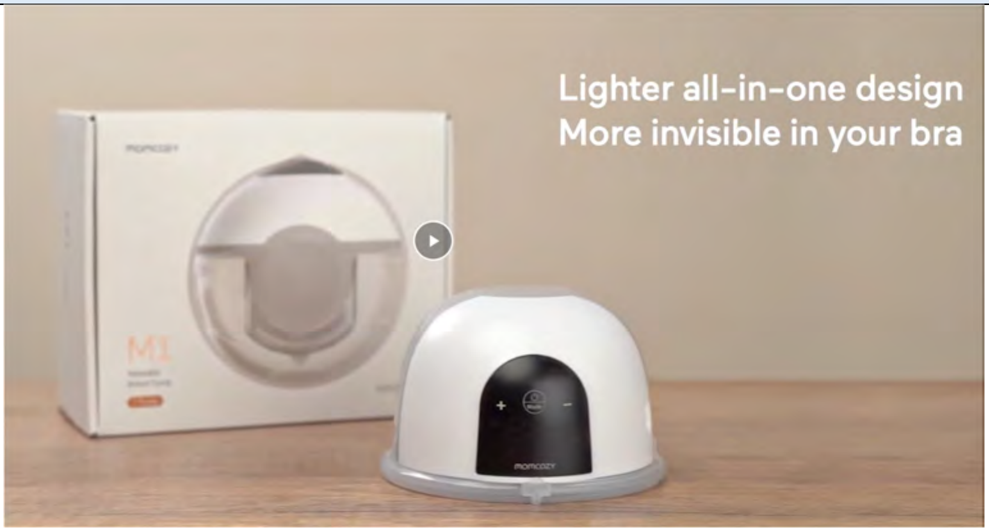
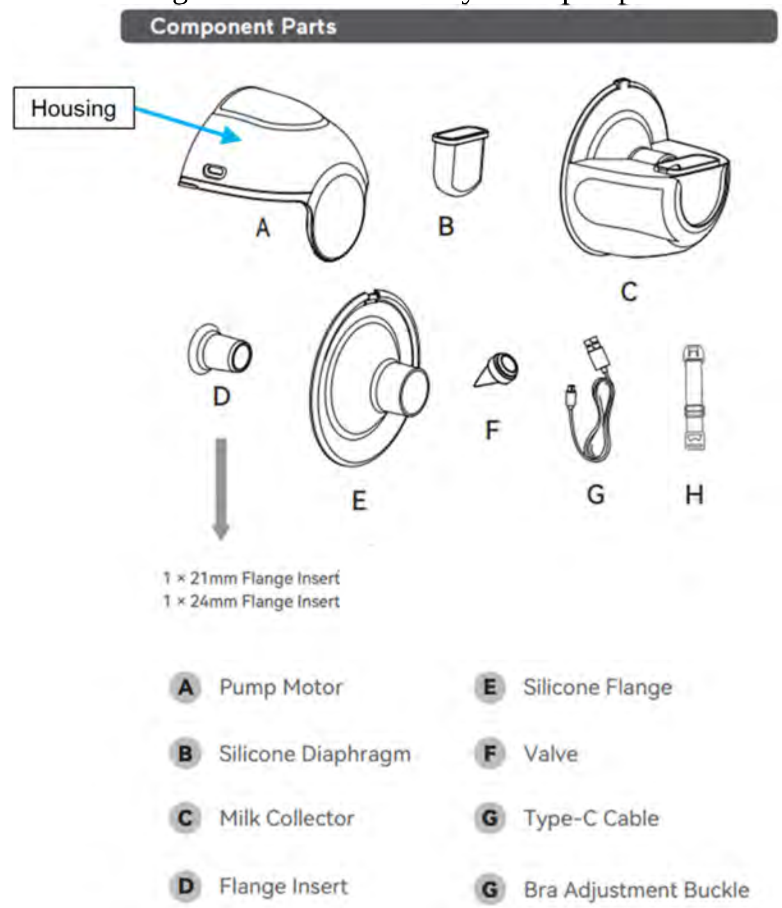
Claim Language		**Momcozy M1**
		 Momcozy M1 Video on Amazon.com (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y, at 2 seconds.)

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

<table>
<tr><th colspan="3">The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M1</th></tr>
<tr><td>1.2</td><td>a housing that includes:

a battery, and

a pump powered by the battery and generating negative air pressure;</td><td>The Momcozy M1 includes a housing that includes a battery and a pump.

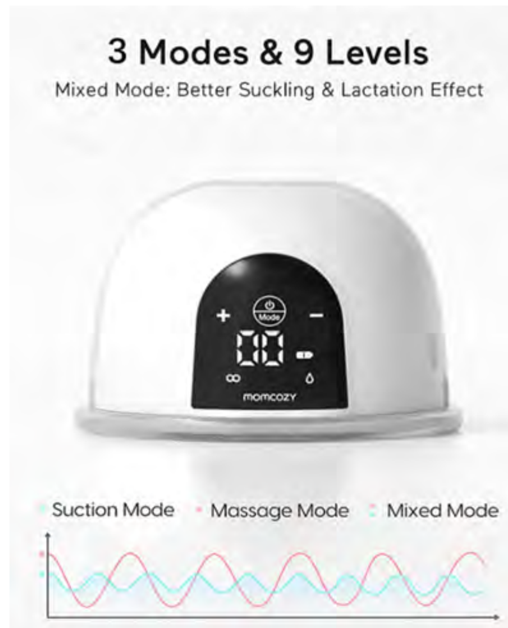


(https://m.media-amazon.com/images/I/A19ypwxs58L.pdf.)</td></tr>
</table>

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

<table>
<tr><th colspan="3">The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M1</th></tr>
<tr><td></td><td></td><td>
The Momcozy M1 housing includes a battery. For example, Momcozy M1 includes a “1200mAh capacity battery, Type-C charging speed is faster, can be used about 90-150 mins / 3-5 times when fully charged.” (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.)

The Momcozy M1 housing includes a pump powered by the battery that generates negative air pressure. The Momcozy Amazon listing states that the “Momcozy wearable breast pump M1 has 3 modes and 9 suction levels.” (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.)



Momcozy M1 Housing showing battery indicator (*Id.*)
</td></tr>
</table>

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

<table>
<tr><th colspan="3">The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M1</th></tr>
<tr><td>1.3</td><td>a breast shield made up of a breast flange and a nipple tunnel;</td><td>The Momcozy M1 includes a breast shield that includes a breast flange and a nipple tunnel.


The Momcozy website indicates that the M1 device includes a breast shield with sizes of “21/24/27mm.” (https://www.momcozy.net/products/double-all-in-one-wearable-breast-pump-m1.)</td></tr>
</table>

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

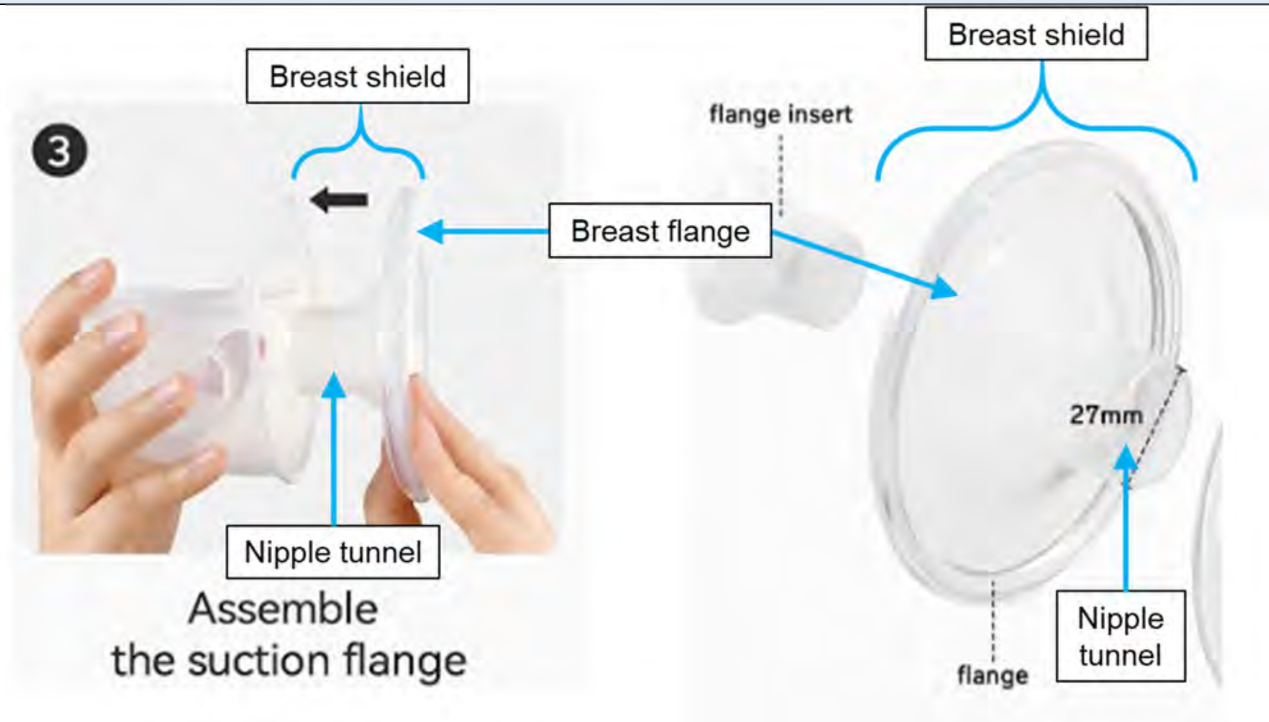
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M1**
		 Momcozy Breast shield images (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.)

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

<table>
<tr><th colspan="3">The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M1</th></tr>
<tr><td>1.4</td><td>a milk container that is configured to be attached to and removed from the housing; and</td><td>The Momcozy M1 includes a milk container.


The Momcozy website indicates that the M1 has a “Milk Collector (150ml)” (https://www.momcozy.net/products/double-all-in-one-wearable-breast-pump-m1.)

The Momcozy M1 milk container is configured to be attached to and removed from the housing.</td></tr>
</table>

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

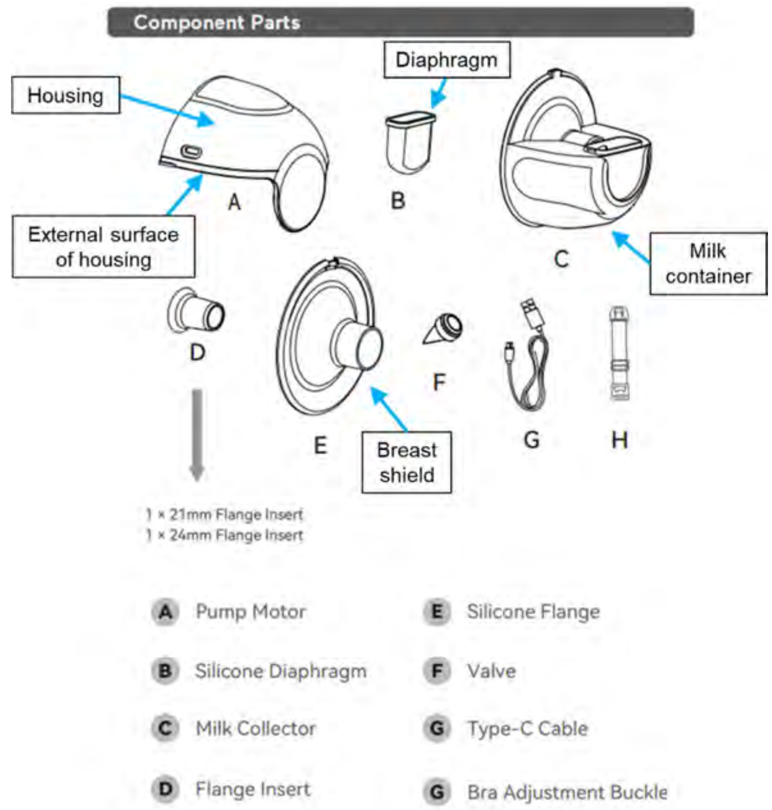
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
	Claim Language	**Momcozy M1**
		 Momcozy M1 Device showing milk container attached to and removed from the housing Momcozy provides a “quick installation” guide on Amazon.com that shows how to attach the housing to the milk container (shown below).

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.		
Claim Language		**Momcozy M1**
		 Quick installation of the M1 device (https://www.momcozy.net/products/double-all-in-one-wearable-breast-pump-m1.)

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

<table>
<tr><th colspan="3">The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M1</th></tr>
<tr><td>1.5</td><td>a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing,</td><td>The Momcozy M1 includes a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing.



(https://m.media-amazon.com/images/I/A19ypwxs58L.pdf.)

The Momcozy M1 includes a “Silicone Diaphragm,” as shown above. (https://m.media-amazon.com/images/I/A19ypwxs58L.pdf.) The quick installation instructions show how to assemble the</td></tr>
</table>

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

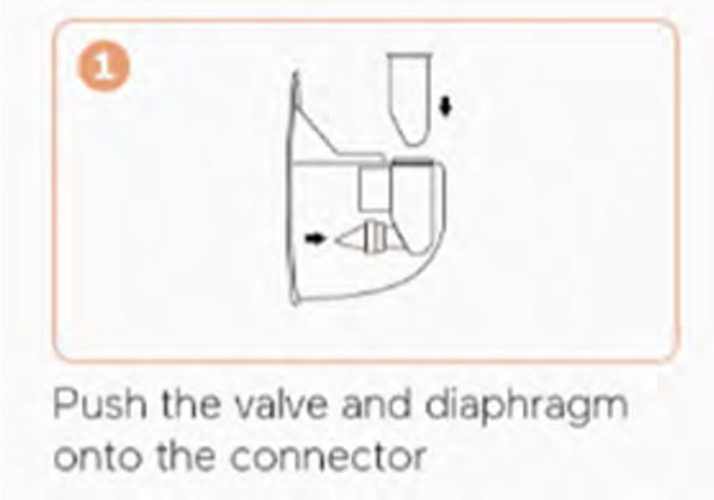
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.		
Claim Language		**Momcozy M1**
		diaphragm into the milk container. (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.)  When the housing is attached onto the milk container, the diaphragm further seats against a diaphragm holder, shown below.

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

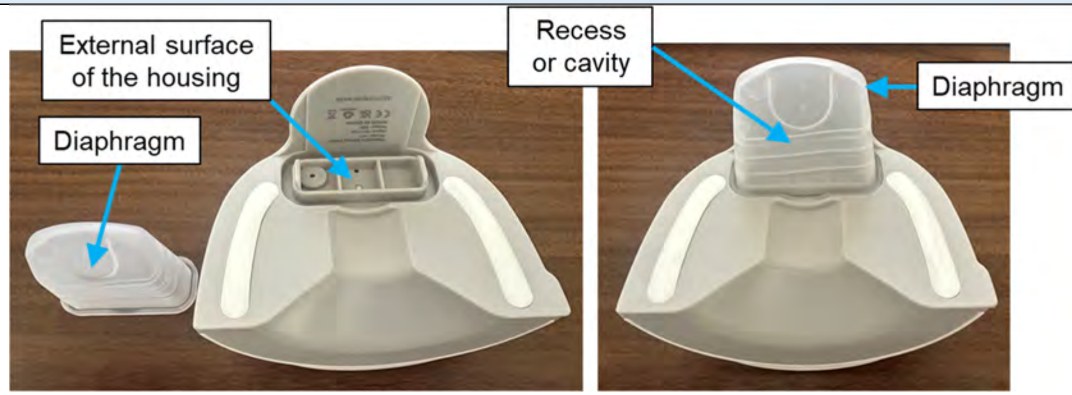
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M1**
		

Exhibit 10 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M1 Product

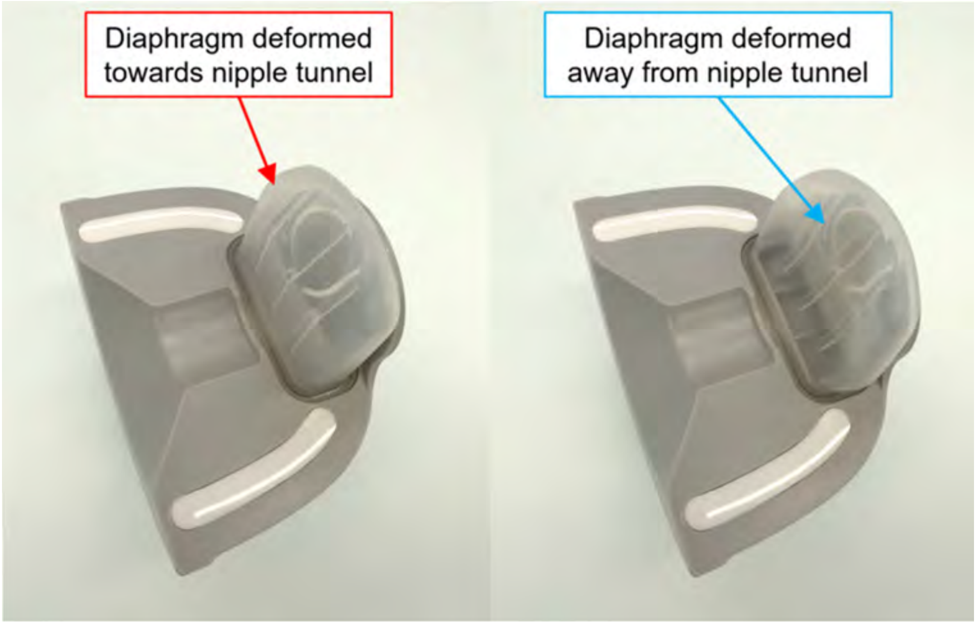
<table>
<tr><th colspan="3">The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M1</th></tr>
<tr><td>1.6</td><td>the diaphragm deforming in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.</td><td>The Momcozy website advertises “9 suction levels” for the Momcozy M1 device. (https://www.momcozy.net/products/double-all-in-one-wearable-breast-pump-m1.) When the pump is operated in the housing, it creates a change in air pressure that deforms the diaphragm, which causes a negative pressure in the nipple tunnel allowing for milk expression. The deformation of the membrane is illustratively shown below:

</td></tr>
</table>

Exhibit 11

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

<table>
<tr><th colspan="3">The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M5</th></tr>
<tr><td colspan="3">Claim 1</td></tr>
<tr><td>1.1</td><td>A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:</td><td>The Momcozy M5 is a breast pump device. The Momcozy M5 is described as an “All-in-one M5 Wearable Breast Pump.” (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump?variant=42648706777286.)

The Momcozy M5 is a breast pump device that is configured as a self-contained device, as shown below.


</td></tr>
</table>

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.	
Claim Language	**Momcozy M5**
	The Momcozy M5 is an in-bra wearable device.  (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.) As shown above, the Momcozy M5 fits inside a user’s bra. Momcozy’s website describes the Momcozy M5 as an “All-in-one M5 Wearable Breast Pump.” (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.) Momcozy provides a “how to use Momcozy M5 Wearable Breast Pump” video on the Momcozy website and is further provided on youtube.com, which instructs a

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

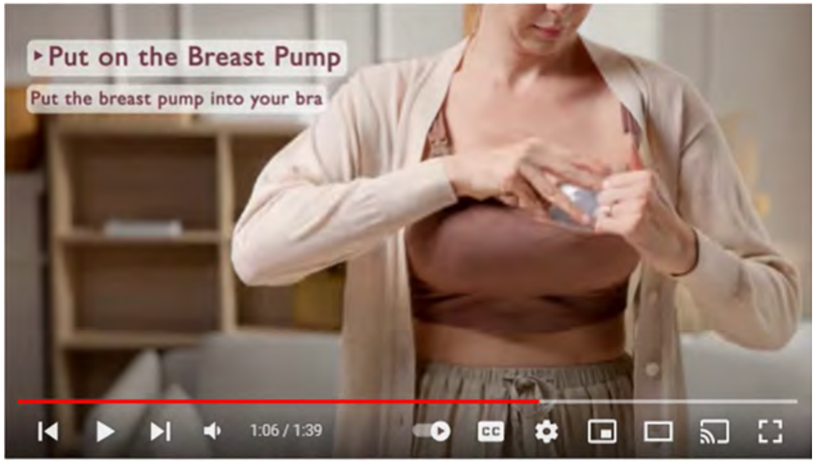
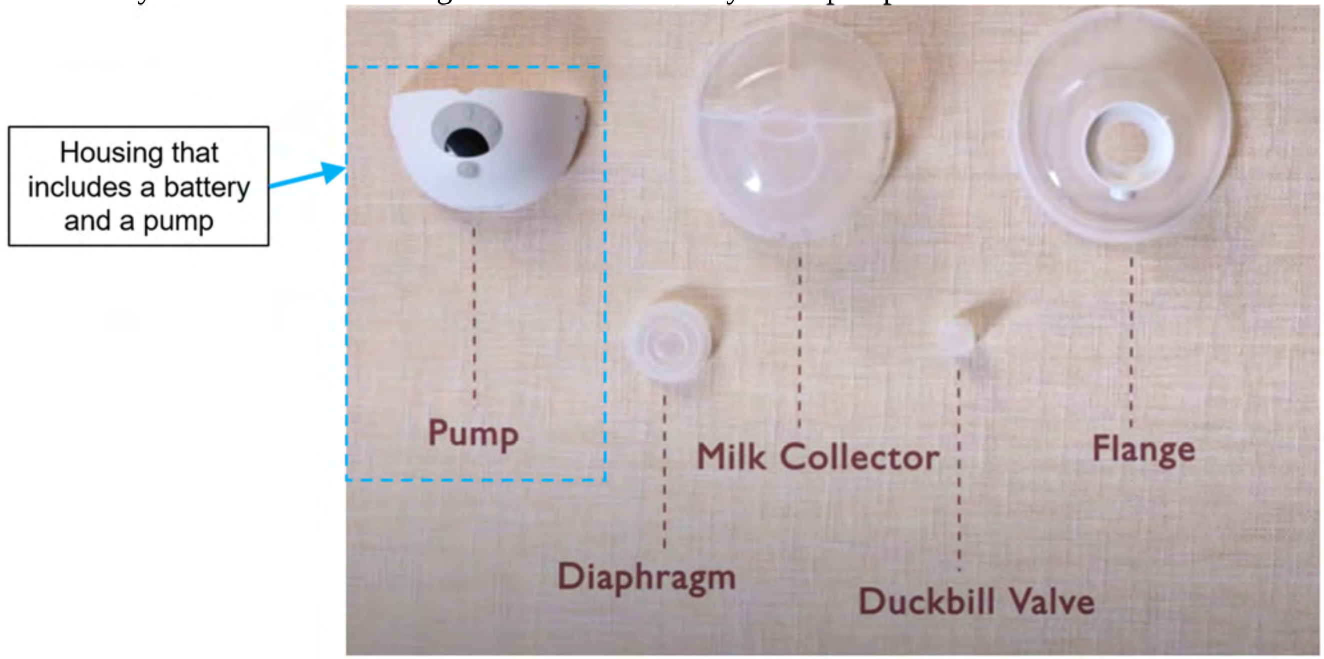
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M5**
		user to “[p]ut the breast pump into your bra.” (https://youtu.be/xNy5KCRf7Uo, at 64 seconds; screen shot reproduced below.) 

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

<table>
<tr><th colspan="3">The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M5</th></tr>
<tr><td>1.2</td><td>a housing that includes:

a battery, and

a pump powered by the battery and generating negative air pressure;</td><td>The Momcozy M5 includes a housing that includes a battery and a pump.


Momcozy M5 “How to use” video (https://youtu.be/xNy5KCRf7Uo, at 32 seconds.)

The Momcozy M5 housing includes a battery. For example, the Momcozy M5 includes a USB-C port in the housing to charge the battery and gives a “charge time [of] about 2 hours, power adapter must be 5V-1A.” (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump)</td></tr>
</table>

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

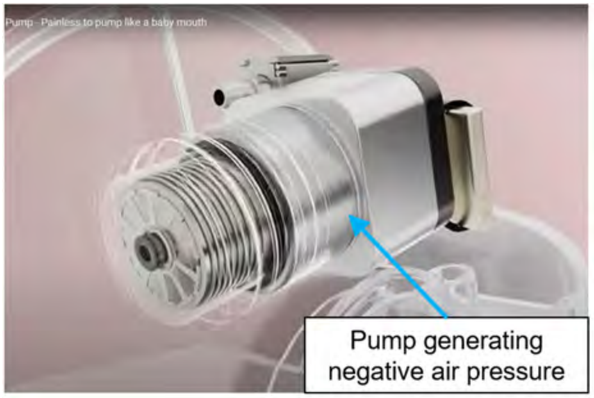
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M5**
		The Momcozy M5 includes a pump powered by the battery that generates negative air pressure. The Momcozy website advertises a “[p]ainless to pump like a baby mouth,” with “9 adjustable suction levels.” (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump) Momcozy shows an illustration of the pump within the housing in the “Momcozy Muse 5” video, reproduced below.  Illustration of Momcozy M5 pump motor (https://youtu.be/roJ3nLLVTgM, at 8 seconds.)

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M5**
1.3	a breast shield made up of a breast flange and a nipple tunnel;	The Momcozy M5 includes a breast shield that includes a breast flange and a nipple tunnel. 

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

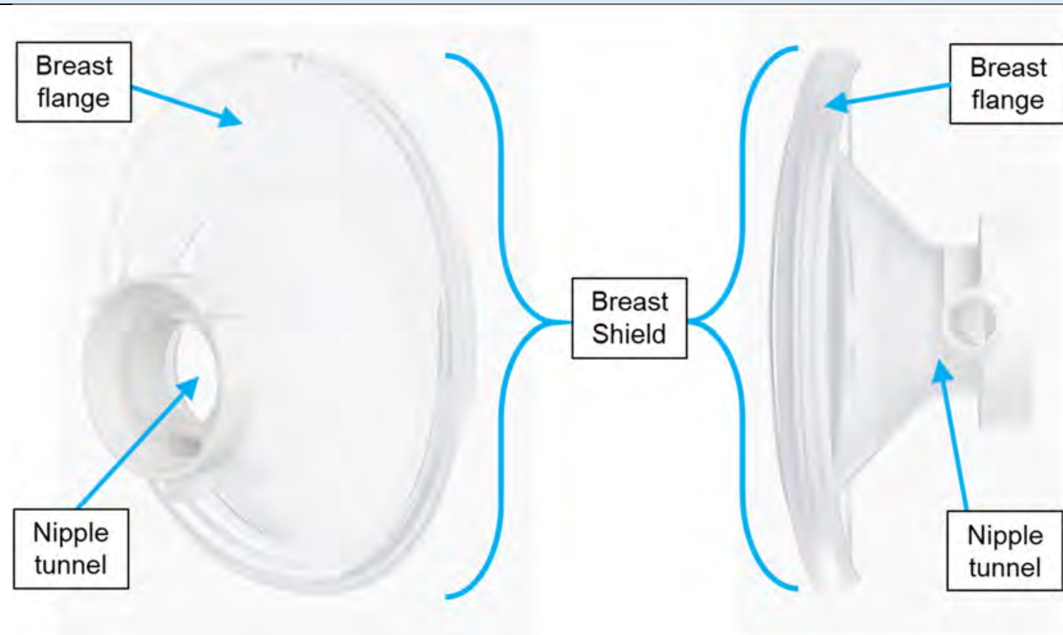
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M5**
		 (https://momcozy.com/products/m5-breast-pump-replacement-parts.)

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

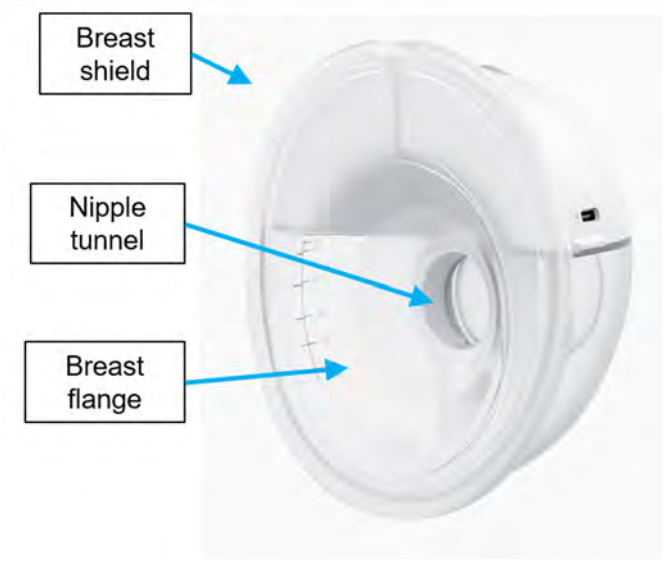
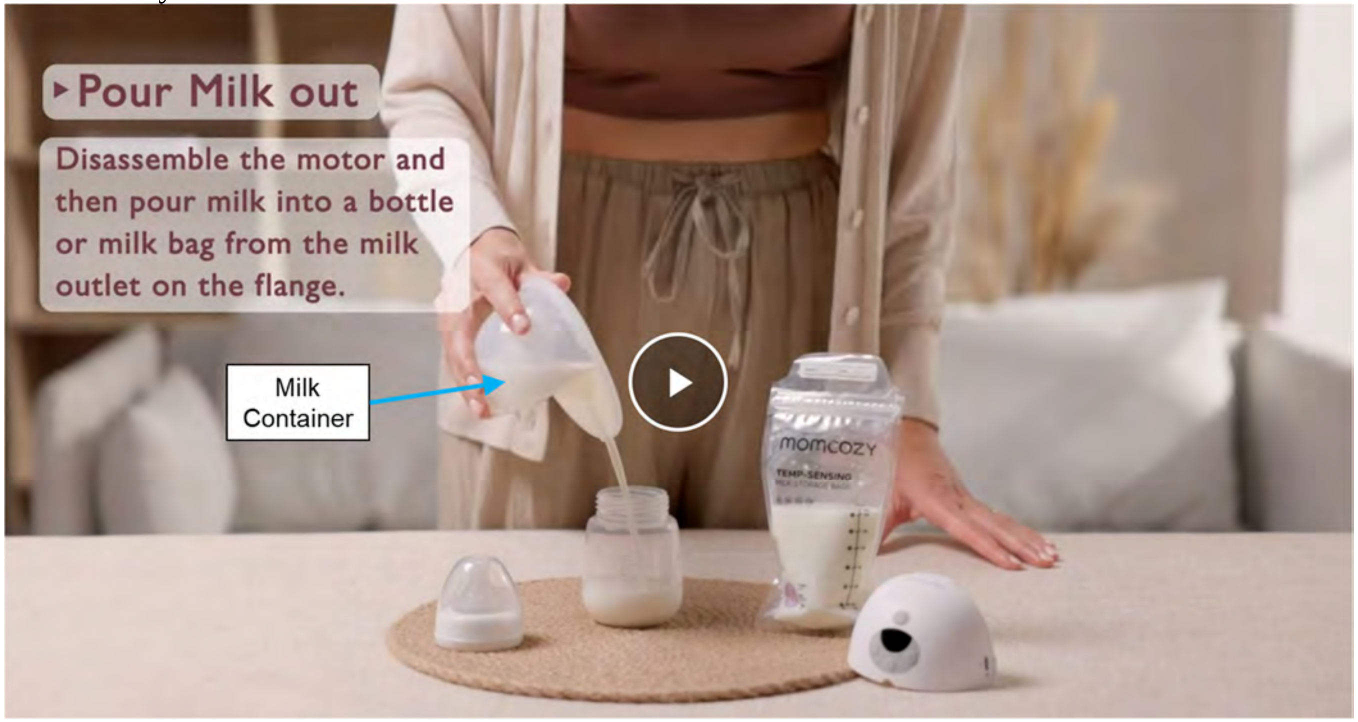
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M5**
		 The Momcozy website indicates that the M5 product includes a breast shield with “flange size: 24mm/27mm,” with the website further detailing a “105° flange slope.” (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.)

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

<table>
<tr><th colspan="3">The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M5</th></tr>
<tr><td>1.4</td><td>a milk container that is configured to be attached to and removed from the housing; and</td><td>The Momcozy M5 includes a milk container.


(https://www.amazon.com/Momcozy-Wearable-Double-Sealed-Electric-Portable/dp/B0B74SJ9SB?th=1.)
(Videos “Momcozy M5 Wearable Breast Pump Use Guide, at 1:34).

The Momcozy website states that the M5 has a “bottle capacity : >120ml.” (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.)</td></tr>
</table>

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

<table>
<tr><th colspan="3">The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M5</th></tr>
<tr><td></td><td></td><td>The milk container is configured to be attached to and removed from the housing.

Momcozy M5 “How to use” video (https://youtu.be/xNy5KCRf7Uo, at 56-60 seconds.)</td></tr>
</table>

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

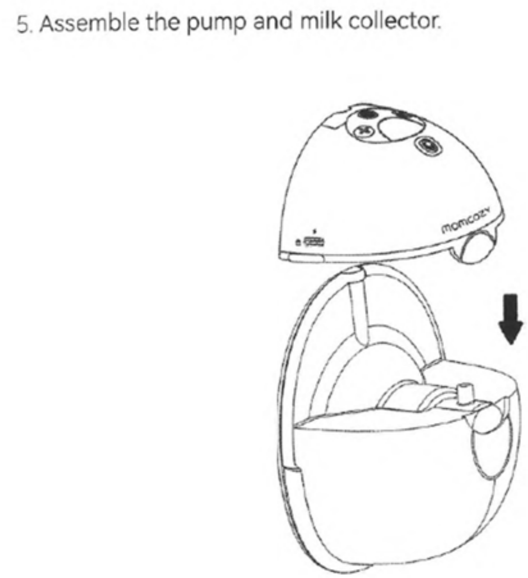
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M5**
		The M5 installation guidelines and user manual also illustrates removal and assembly of the housing to the milk container. (Momcozy, M5 User Manual, pp. 9, 13; *See also* Momcozy, M5 Installation Guidelines, p. 1.) 

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

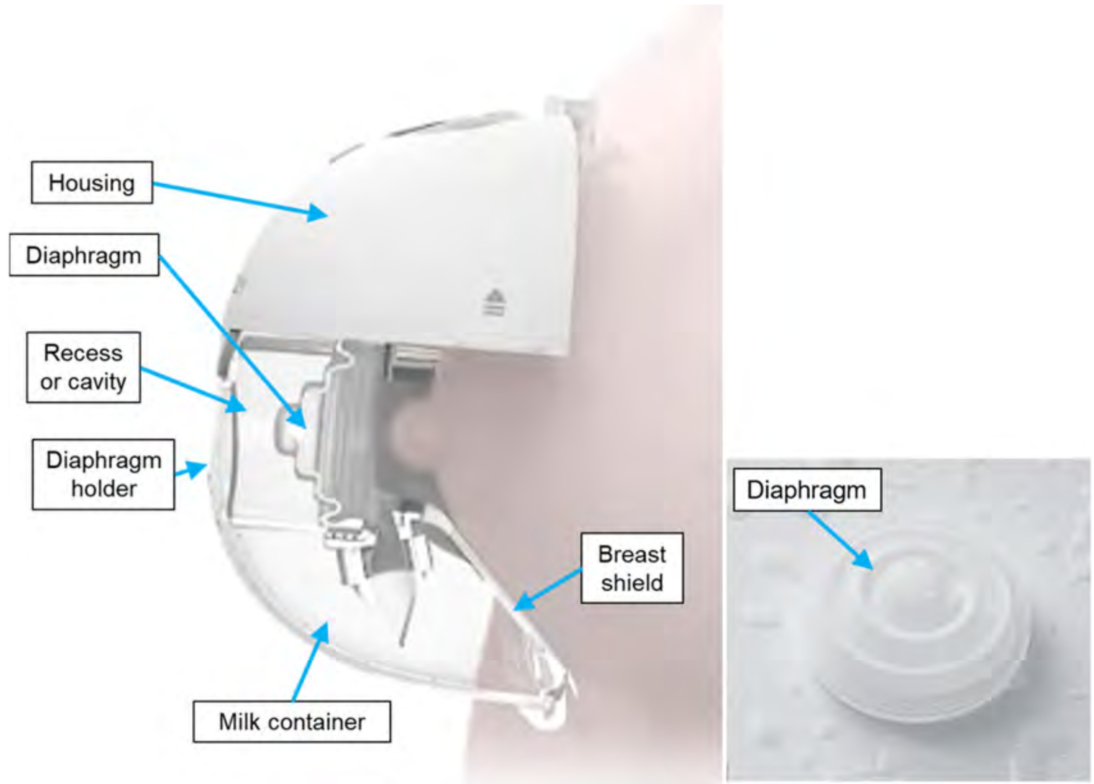
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.		
Claim Language		**Momcozy M5**
1.5	a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing,	The Momcozy M5 includes a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing.  As shown below, Momcozy instructs a user to "[s]nap the diaphragm onto the milk container," referring to the identified diaphragm holder in the annotated picture above. (https://youtu.be/xNy5KCRf7Uo, at 36-42 seconds; screen shot reproduced below.) The edge of the diaphragm holder is circular and matches the size

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.	
Claim Language	**Momcozy M5**
	of the diaphragm. The diaphragm includes a lip around the edge that seats on the rim of the diaphragm holder. The diaphragm is supported by another holder that is attached to the nipple tunnel.  As shown above and below, the diaphragm holder forms a recess or cavity behind the diaphragm and between an external surface of the housing.

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

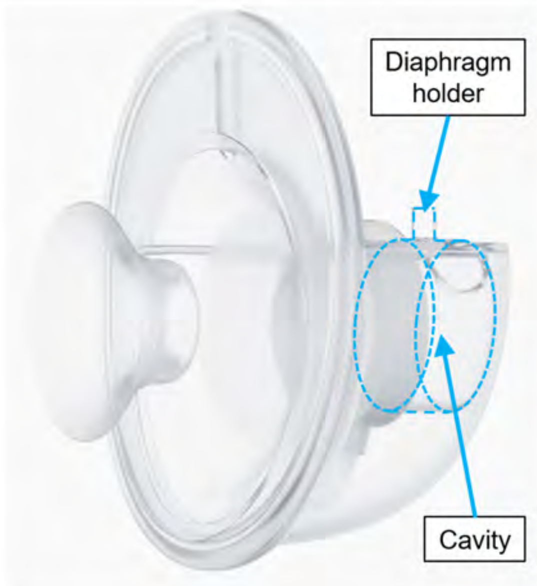
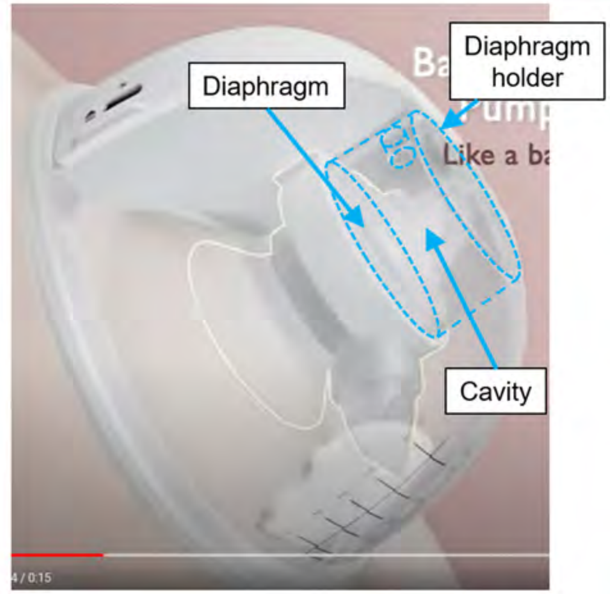
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.	
Claim Language	**Momcozy M5**
	  As shown above, the cavity formed by the diaphragm holder includes a cylinder portion behind supporting the diaphragm and a narrow tube portion in contact with the external surface of the housing.

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M5**
		
1.6	the diaphragm deforming in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.	The Momcozy M5 includes a diaphragm that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. The Momcozy website advertises “9 adjustable suction levels” for the M5 device. (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.) The “Momcozy Muse 5” video, still images reproduced below, shows the deforming movement of the diaphragm that creates negative air pressure in the nipple tunnel.

Exhibit 11 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy M5 Product

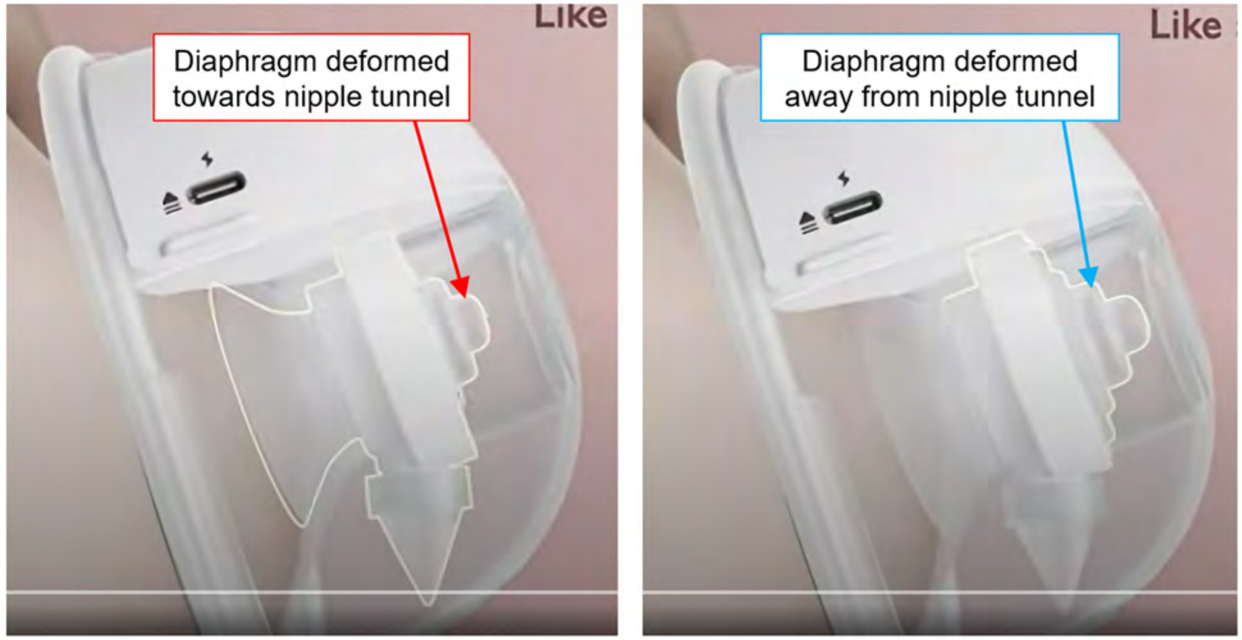
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy M5**
		 Illustrative video of Momcozy M5 deforming diaphragm (https://youtu.be/roJ3nLLVTgM, at 2-7 seconds.)

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Exhibit 12

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td colspan="3">Claim 1</td></tr>
<tr><td>1.1</td><td>A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:</td><td>The Momcozy S12 Pro is a breast pump device. The Momcozy website states that the Momcozy S12 Pro is a “Wearable Breast Pump.” (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.)

The Momcozy S12 Pro is a breast pump device that is configured as a self-contained device, as shown below.


</td></tr>
</table>

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td></td><td></td><td>The Momcozy S12 Pro is an in-bra wearable device.


(https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.)

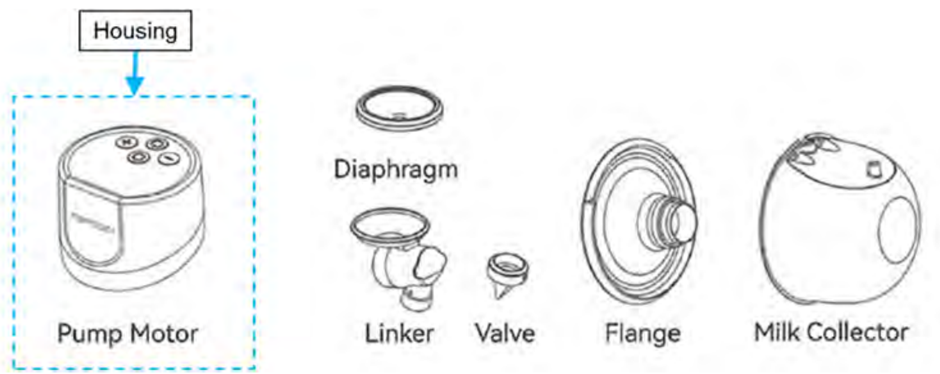
The website states that “this bra-fit wearable breast pump allows for ultimate free pumping on the go for multitasking and body motion to exercise, which is a shortcut for moms to get the balance of nursing babies and regain normal lives.” (Id.) Additionally, the Momcozy website discloses that “[Momcozy’s] hands-free breast pump is designed to be worn with your standard nursing bra.” (Id.)</td></tr>
</table>

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td>1.2</td><td>a housing that includes:

a battery, and

a pump powered by the battery and generating negative air pressure;</td><td>The Momcozy S12 Pro includes a housing that includes a battery and a pump.



Momcozy S12 Pro Quick guide, p. 2

The Momcozy S12 Pro housing includes a battery. For example, the Momcozy S12 Pro user guide states that “[w]hen charging, the battery indicator lights up one by one, displaying increasing battery percentage from 25%, 50%, 75%, to 100%.” (Momcozy S12 Pro User Guide, p. 13.)

The Momcozy S12 Pro housing includes a pump powered by the battery that generates negative air pressure. The Momcozy S12 Pro user guide also identifies the housing has the “pump motor,” stating that “[t[he breast pump has 9 suction levels to choose from.” (Momcozy, S12 Pro User Manual, pp. 3, 5, 7.)</td></tr>
</table>

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

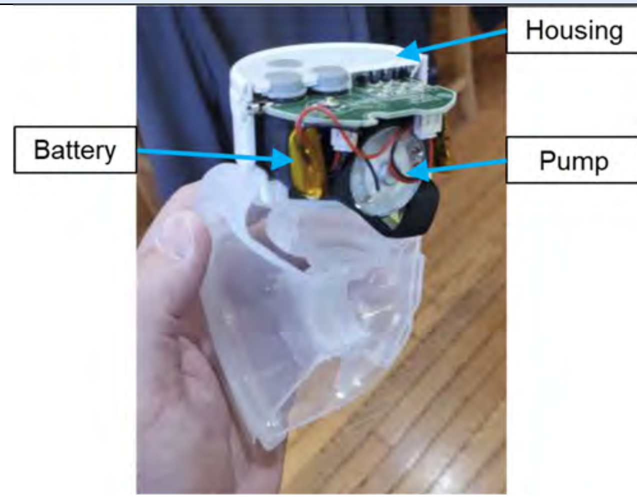
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S12 Pro**
		 Momcozy S12 Pro internal components.

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

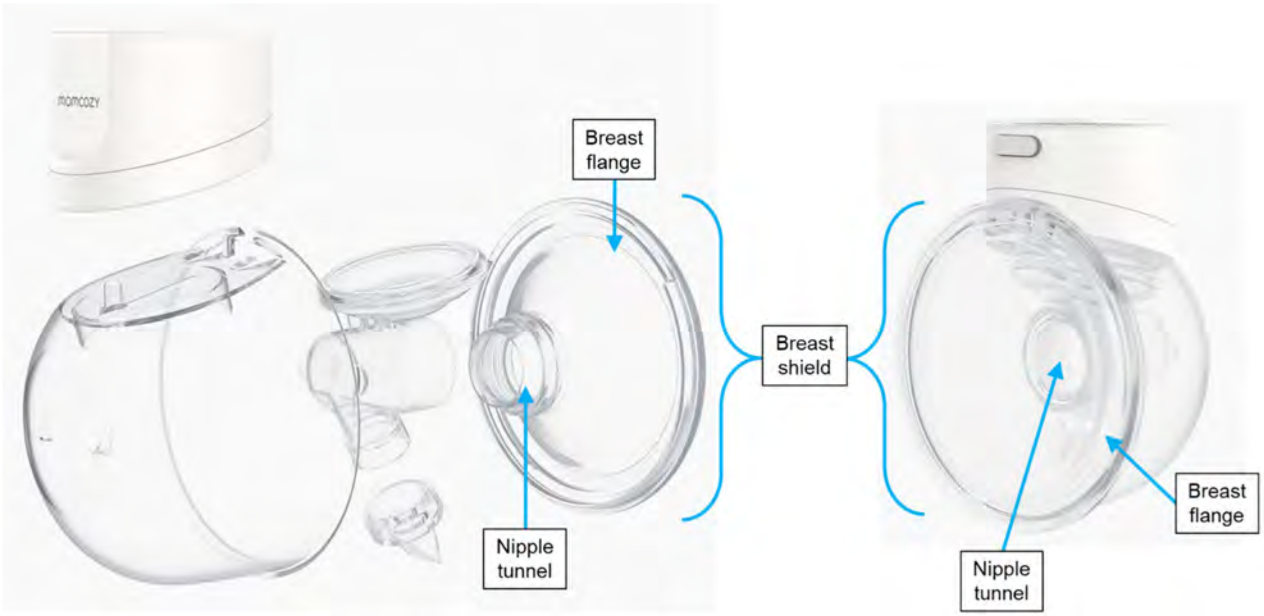
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S12 Pro**
1.3	a breast shield made up of a breast flange and a nipple tunnel;	The Momcozy S12 Pro includes a breast shield made up of a breast flange and a nipple tunnel.  (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.) The Momcozy website indicates that the S12 Pro product includes a “silicone flange (24 mm).” (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump?variant=42641714741446.)

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td>1.4</td><td>a milk container that is configured to be attached to and removed from the housing; and</td><td>The Momcozy S12 Pro includes a milk container that is configured to be attached to and removed from the housing. The Momcozy website clarifies that the S12 Pro product includes a “milk collector (180ml).” (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump?variant=42641714741446.)


(https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.)</td></tr>
</table>

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td></td><td></td><td>


The Momcozy S12 Pro Quick Guide and User Guide also illustrates removal and assembly of the housing to the milk container. (Momcozy, S12 Pro Quick guide, p. 1; *See also* Momcozy, S12 Pro User Manual, pp. 9, 13.)
</td></tr>
</table>

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

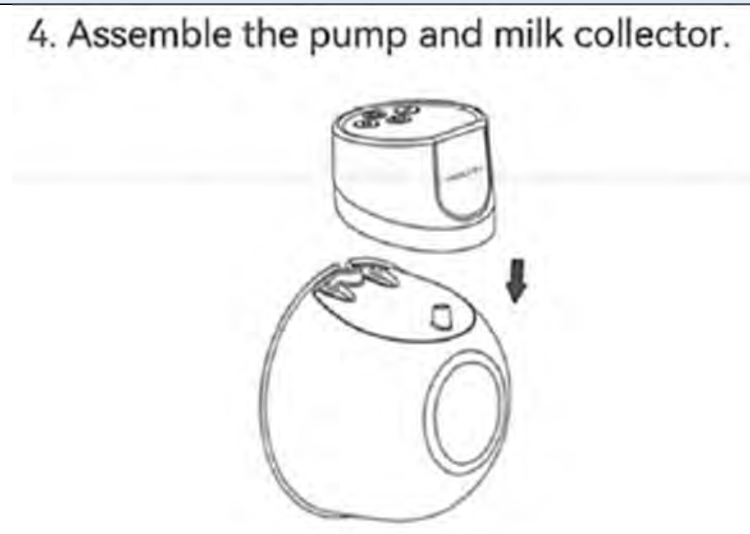
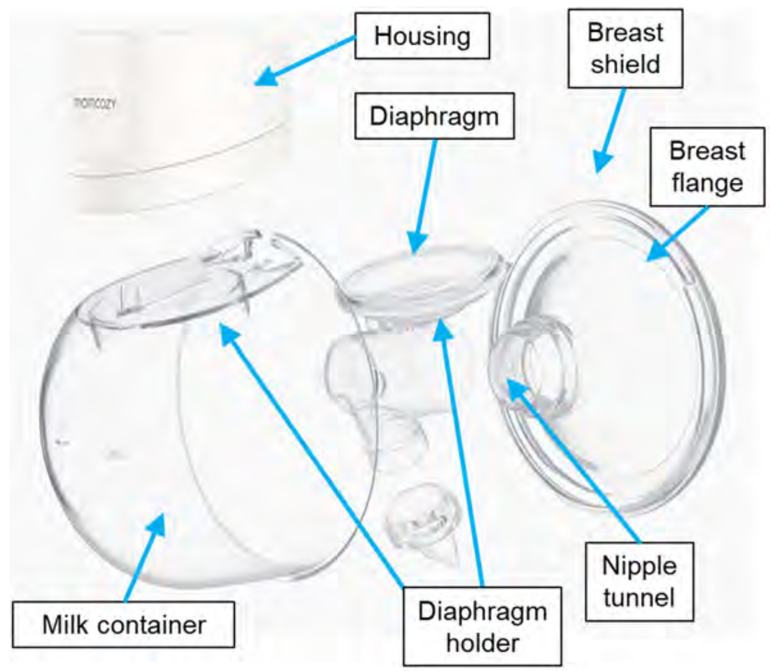
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.	
Claim Language	**Momcozy S12 Pro**
	

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td>1.5</td><td>a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing,</td><td>The Momcozy S12 Pro includes a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing.


As shown below, the Momcozy S12 Pro includes a diaphragm.

The Momcozy website indicates that the S12 Pro product includes a “silicone diaphragm.” (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump?variant=42641714741446)</td></tr>
</table>

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

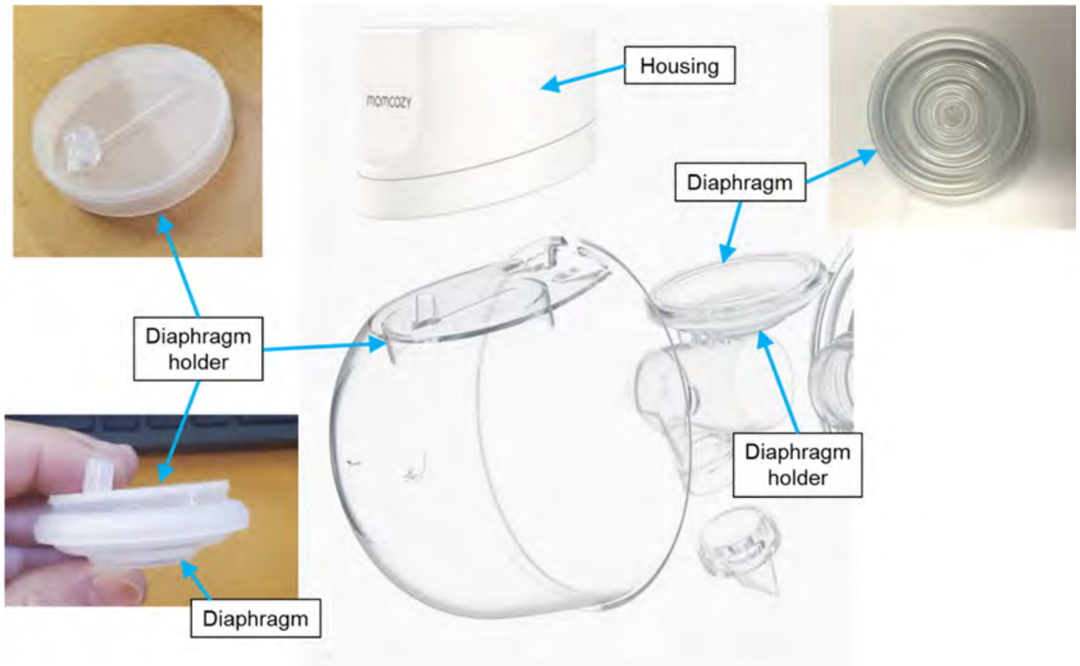
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S12 Pro**
		As shown below, the diaphragm is configured to be seated against a diaphragm holder that forms a recess or cavity above the diaphragm and between an external surface of the housing. The S12 Pro integrates the diaphragm holder into the milk container, but for clarity, the picture below shows the diaphragm holder as a single component with the milk container removed.  (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.) As shown above, the cavity formed by the diaphragm holder includes a wide portion in direct contact with the diaphragm, a narrow portion in contact with the external surface of the housing, and a channel to provide an even distribution of negative pressure to the diaphragm. The cavity, bound by the wide and narrow portions, provides an unrestricted air channel from suction source to diaphragm.

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

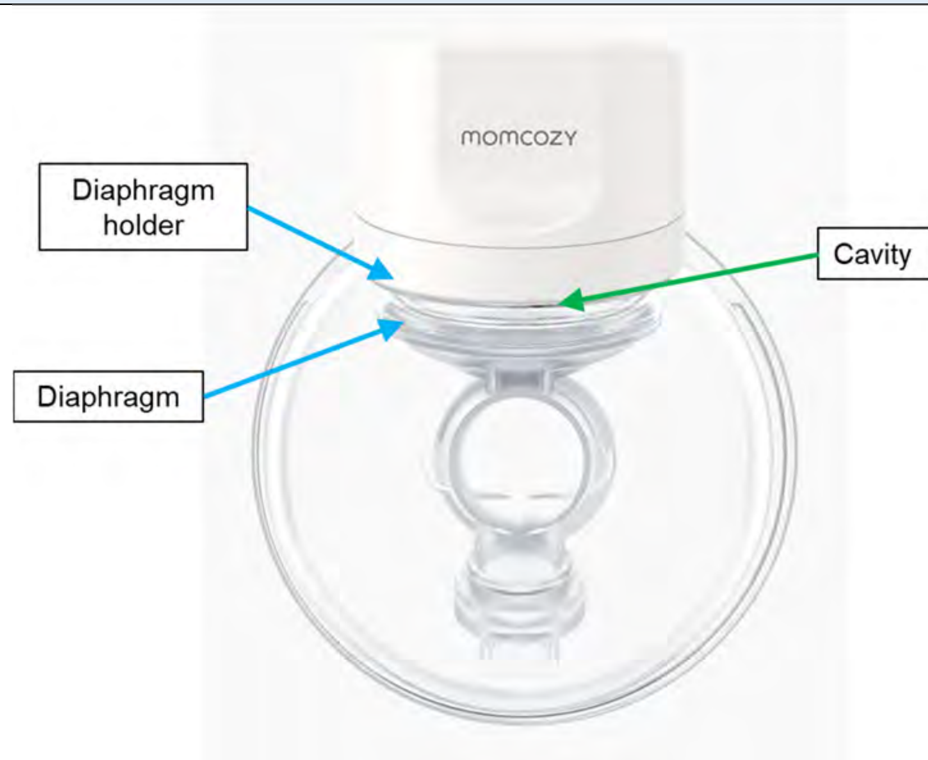
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S12 Pro**
		

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.	
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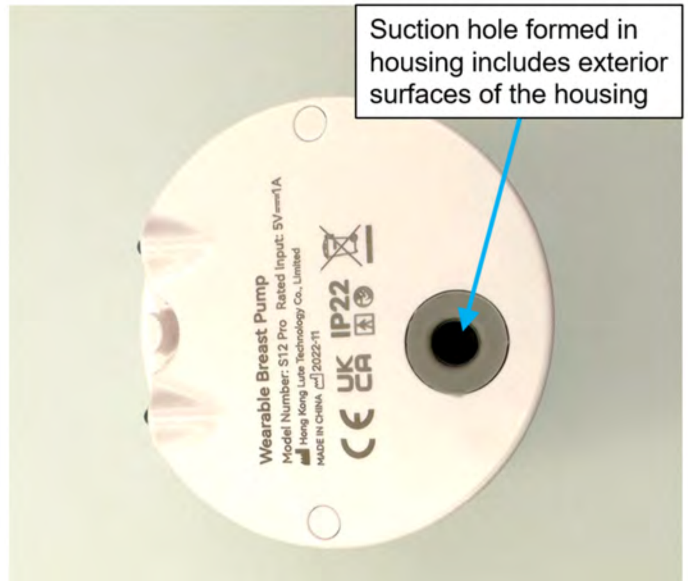
	

Exhibit 12 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Pro Product

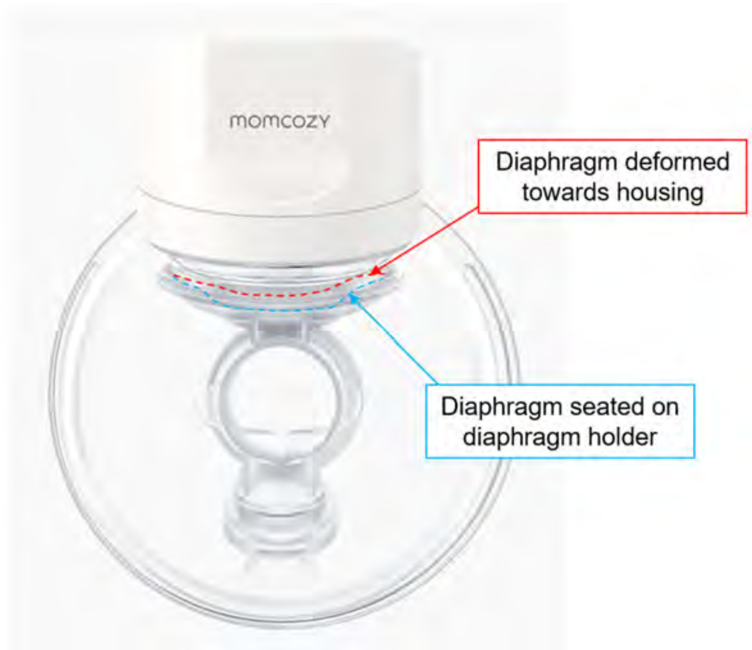
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S12 Pro**
1.6	the diaphragm deforming in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.	The Momcozy S12 Pro includes the diaphragm which deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. The Momcozy S12 Pro User Guide also identifies that “[t[he breast pump has 9 suction levels to choose from.” (Momcozy, S12 Pro User Manual, p. 5.) On information and belief, when the pump is operated in the housing, it creates a change in air pressure that deforms the membrane to create negative pressure in the nipple tunnel. 

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Exhibit 13

Exhibit 13 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Product

<table>
<tr><th colspan="3">The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12</th></tr>
<tr><td colspan="3">Claim 1</td></tr>
<tr><td>1.1</td><td>A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:</td><td>The Momcozy S12 is a breast pump device. The Momcozy S12 is described as “9 Levels Wearable Electric Breast Pump - S12.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

The Momcozy S12 is a breast pump device that is configured as a self-contained device, as shown below.


</td></tr>
</table>

Exhibit 13 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.		
Claim Language		**Momcozy S12**
		The Momcozy S12 is an in-bra wearable device.  (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The Momcozy S12 is described as a "Wearable Breast Pump." (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The Momcozy S12 can "[f]it for any standard nursing bra." (*Id.*)

Exhibit 13 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Product

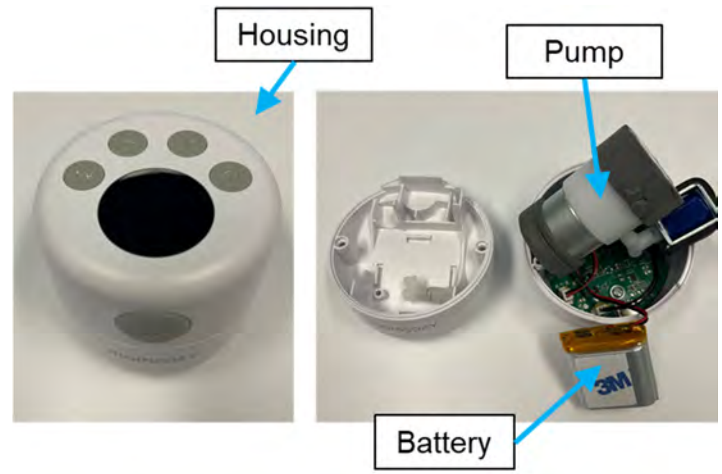
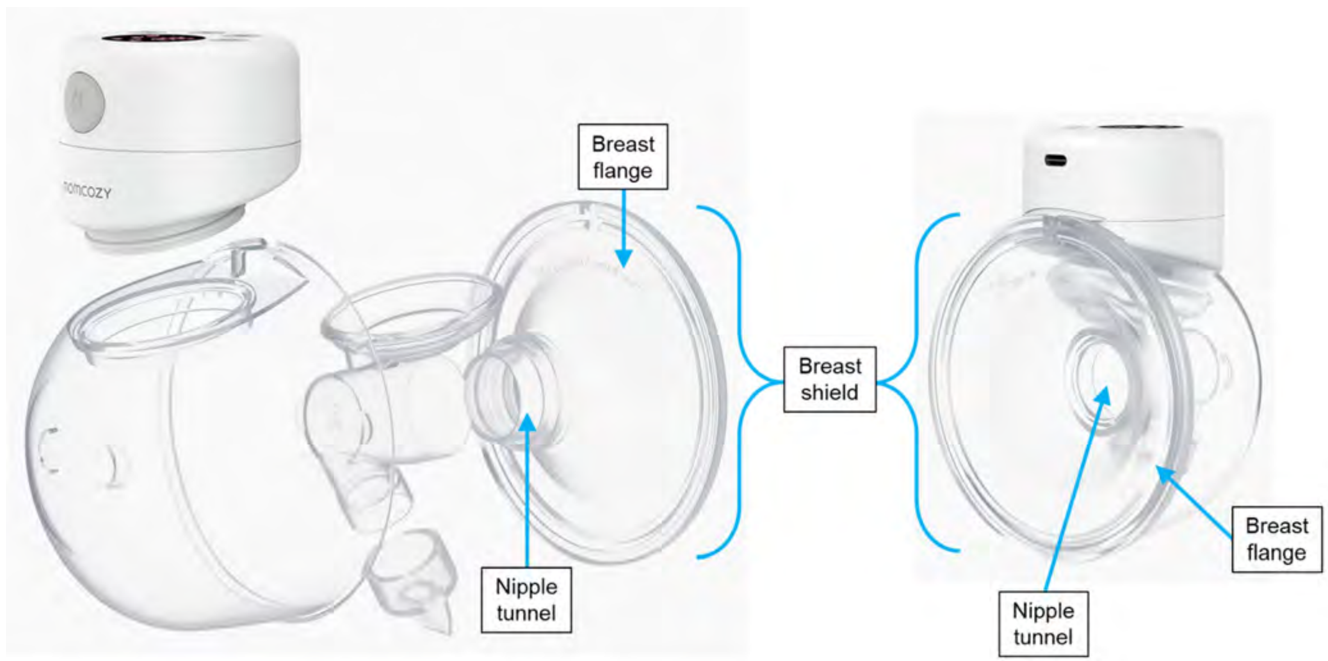
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S12**
1.2	a housing that includes: a battery, and a pump powered by the battery and generating negative air pressure;	The Momcozy S12 includes a housing that includes a battery and a pump. The Momcozy S12 includes a housing, as shown below.  The Momcozy S12 pump housing includes a battery. For example, the Momcozy S12 user guide also states that “[t]his product has a built-in battery,” and that they “recommend that you use a certified 5V==1A adapter to charge the Pump Motor.” (Momcozy, S12 User Manual, p. 2.) The Momcozy website states that the Momcozy S12 is “[c]hargeable.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) On information and belief, the Momcozy S12 pump housing includes a power charging circuit for controlling the charging of the rechargeable battery and control electronics powered by the rechargeable battery because the Momcozy S12 is rechargeable and it has buttons that change the operation of the pump. (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

Exhibit 13 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Product

<table>
<tr><th colspan="3">The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12</th></tr>
<tr><td></td><td></td><td>The Momcozy website advertises that “[t]his [S12] hands-free pump can be placed in the nursing bra so that you can pump milk anytime and anywhere. The wearable breastfeeding pump gives you the freedom to do multitasks during milk pumping.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The website also states that the S12 breast pump has “9 Adjustable Suction Levels.” (Id.)</td></tr>
<tr><td>1.3</td><td>a breast shield made up of a breast flange and a nipple tunnel;</td><td>The Momcozy S12 includes a breast shield made up of a breast flange and a nipple tunnel.


(https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)</td></tr>
</table>

Exhibit 13 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Product

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<tr><th colspan="3">The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12</th></tr>
<tr><td></td><td></td><td>The Momcozy website indicates that the S12 Pro product includes a “Flange Size: 24mm.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)</td></tr>
<tr><td>1.4</td><td>a milk container that is configured to be attached to and removed from the housing; and</td><td>The Momcozy S12 includes a milk container that is configured to be attached to and removed from the housing. The Momcozy website clarifies that the S12 product includes a “milk collector (180ml/6oz).” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)


(https://www.youtube.com/watch?v=gQ0N_oNCJs0 at 0:24.)</td></tr>
</table>

Exhibit 13 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Product

<table>
<tr><th colspan="3">The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
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<tr><td></td><td></td><td>

(https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

The S12 user guide also illustrates removal and attachment of the housing to the milk container, as shown below. (Momcozy, S12 User Manual, p. 10.)</td></tr>
</table>

Exhibit 13 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Product

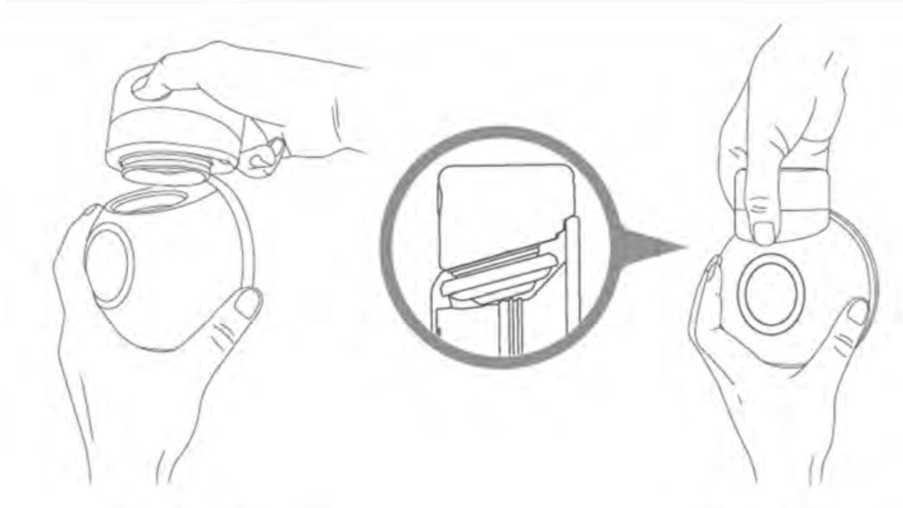
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S12**
		 (Picture 1) (Picture 2)

Exhibit 13 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Product

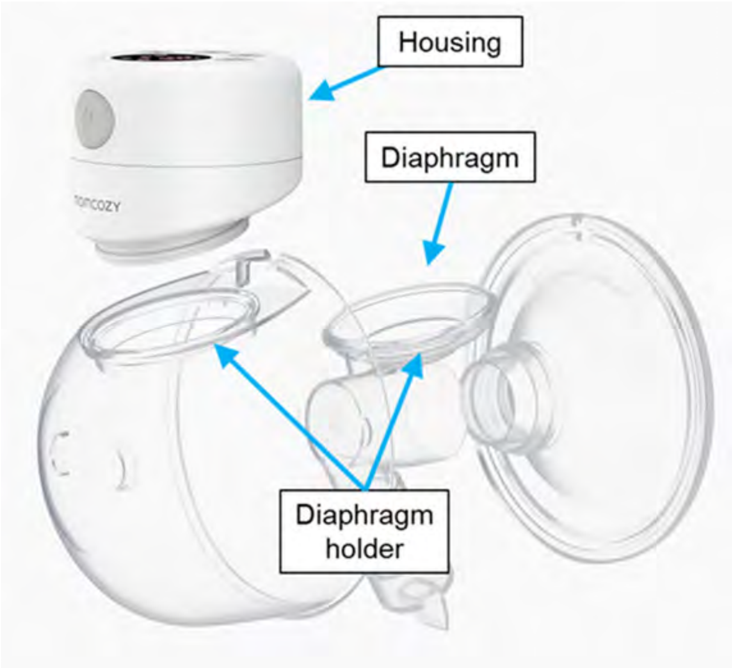
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S12**
1.5	a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing,.	The Momcozy S12 includes a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing. As shown below, the Momcozy S12 includes a diaphragm.  (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The Momcozy website indicates that the S12 product includes a “silicone diaphragm.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

Exhibit 13 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Product

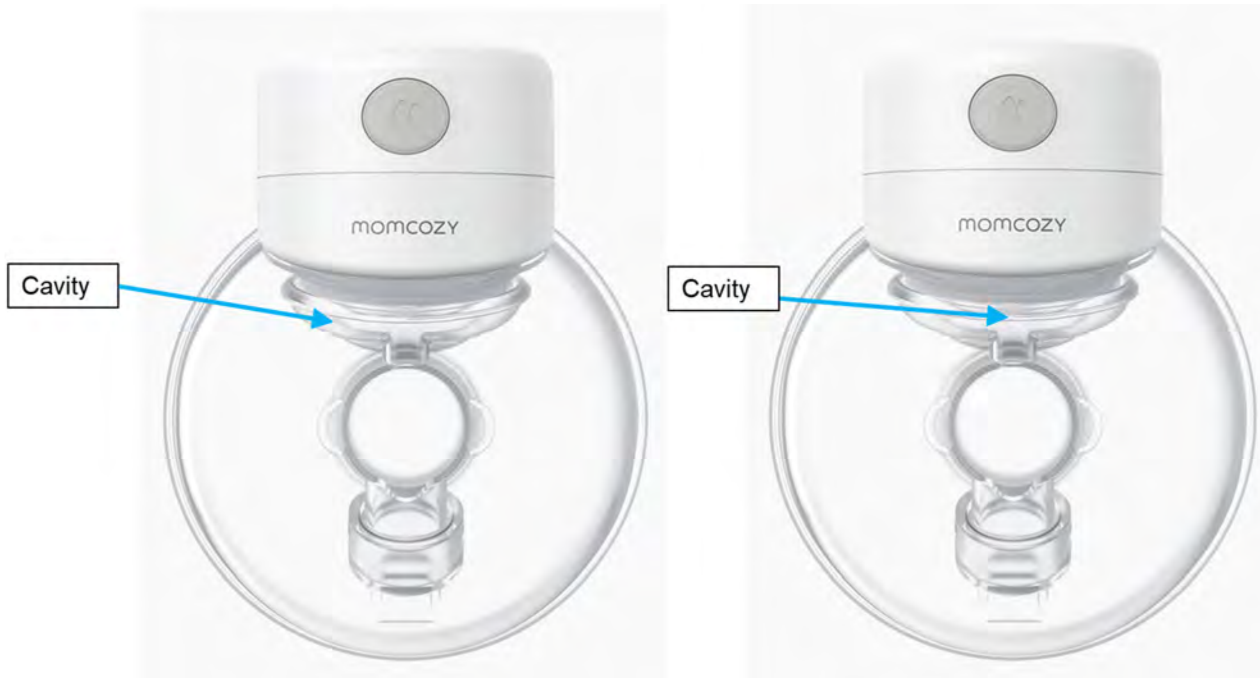
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S12**
		The diaphragm extends into the diaphragm holder and forms a cavity with the housing, as shown below.  (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

Exhibit 13 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S12 Product

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<tr><th colspan="3">The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12</th></tr>
<tr><td>1.6</td><td>the diaphragm deforming in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.</td><td>The Momcozy S12 includes a diaphragm that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

The Momcozy S12 product is advertised as having “9 adjustable suction levels and 2 modes.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) On information and belief, when the pump is operated in the housing, it creates a change in air pressure that deforms the diaphragm to create negative pressure in the nipple tunnel.

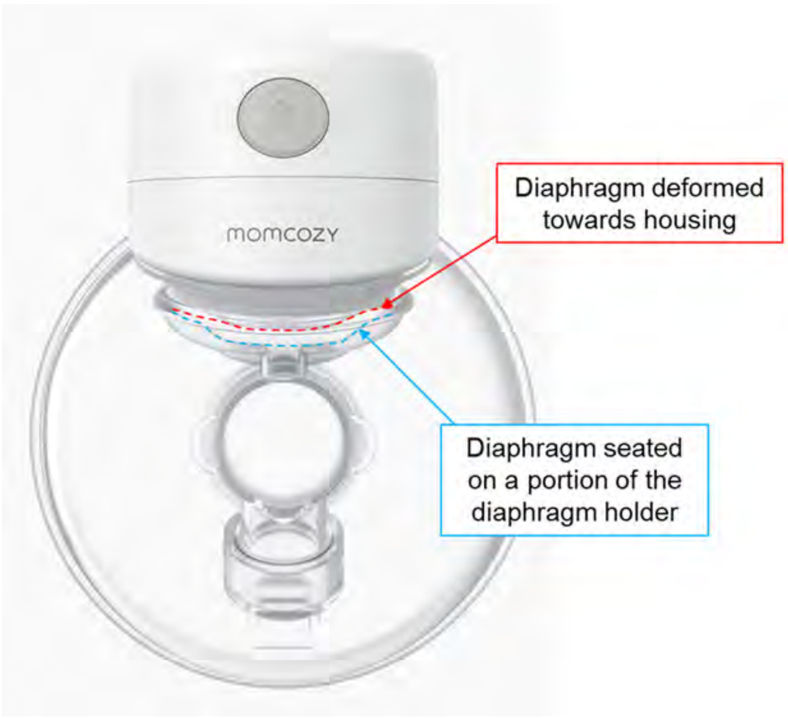
</td></tr>
</table>

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Exhibit 14

Exhibit 14 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.		
Claim Language		**Momcozy S9 Pro**
Claim 1		
1.1	A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:	The Momcozy S9 Pro is a breast pump device. The Momcozy S9 Pro is described as the "S9 Pro Wearable Breast Pump." (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.) The Momcozy S9 Pro is a breast pump device that is configured as a self-contained device. 

Exhibit 14 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9 Pro**
		The Momcozy S9 Pro is an in-bra wearable device. The Momcozy website states that the Momcozy S9 Pro “is designed to be worn with your standard nursing bra.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)  (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)

Exhibit 14 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Pro Product

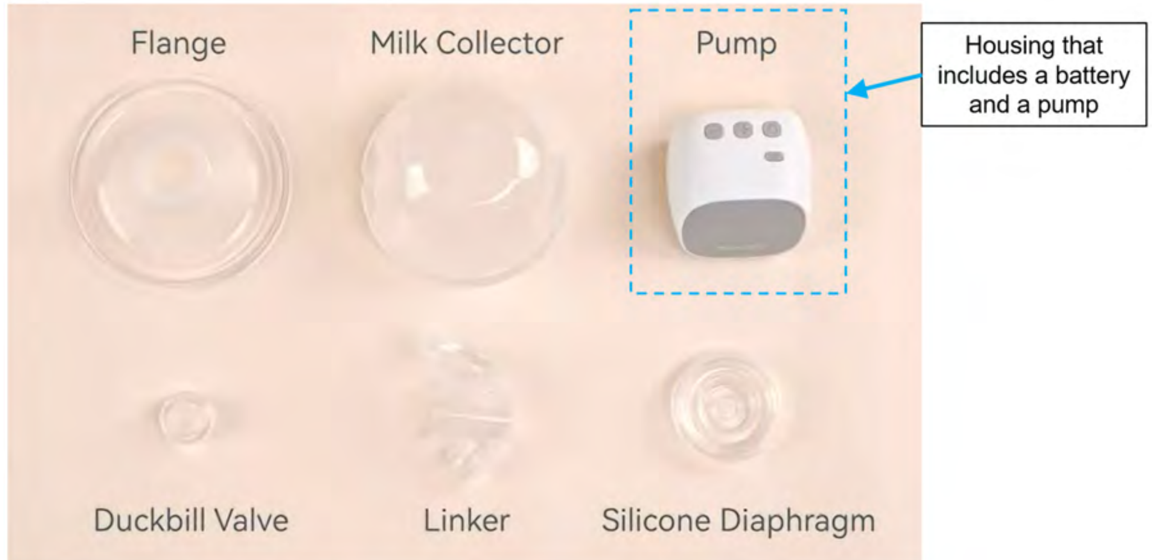
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9 Pro**
1.2	a housing that includes: a battery, and a pump powered by the battery and generating negative air pressure;	The Momcozy S9 Pro includes a housing that includes a battery and a pump.  Still image from Momcozy S9 Pro video (https://www.amazon.com/Momcozy-S9-Pro-Wearable-Hands-Free/dp/B0B74TFJCF?th=1.) The Momcozy S9 Pro housing includes a battery. For example, the Momcozy S9 Pro user guide provides details on charging the battery. (Momcozy S9 Pro User Guide, p. 13.) The Momcozy website describes the Momcozy S9 Pro as “Long Battery Life.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.) The Momcozy S9 Pro housing includes a pump powered by the battery that generates negative air pressure. The Momcozy website advertises that the Momcozy S9 Pro includes a “Pump motor” and that the “S9 Pro hands-free pumps in a better efficiency with less time, saving more time for moms.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump?variant=42680176738502.)

Exhibit 14 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Pro Product

<table>
<tr><th colspan="3">The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9 Pro</th></tr>
<tr><td></td><td></td><td>The Momcozy website describes the Momcozy S9 Pro as having “Hospital grade 280 ~ 300mmHg suction range.” (Id.) The Momcozy S9 Pro pump generates negative air pressure. For example, the Momcozy website states that the Momcozy S9 Pro breast pump has “S9 Pro breast pump owns 2 modes of expression and mixed suction with 9 intensity levels for each.” (Id.)

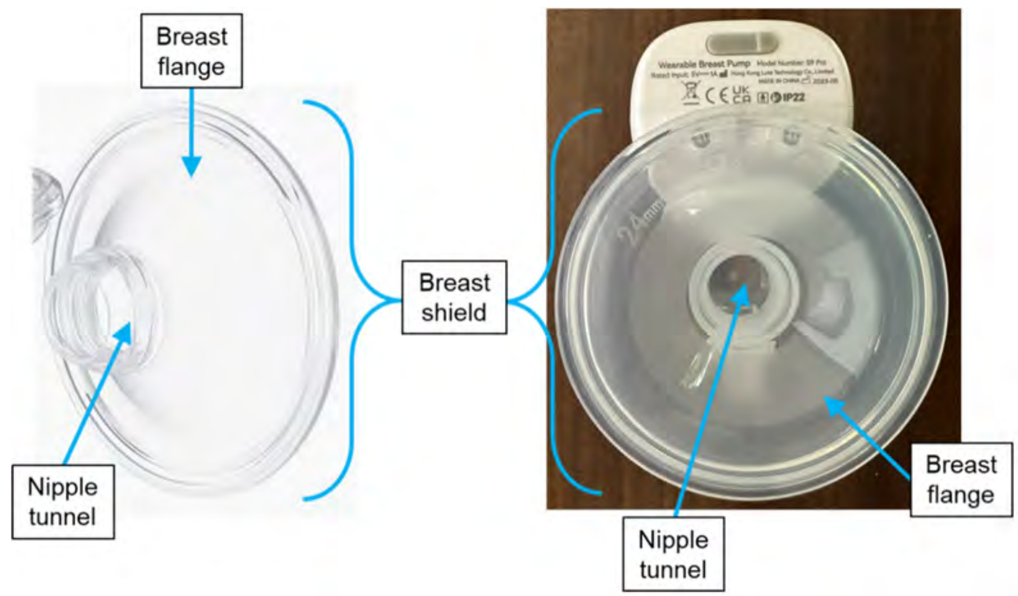
The Momcozy S9 Pro user guide also states that the “Momcozy pump has 9 vacuum pressure settings for each mode, giving you control over what feels comfortable and works most efficiently in both stimulation and expression modes.” (Momcozy S9 Pro User Guide, p. 12.)</td></tr>
<tr><td>1.3</td><td>a breast shield made up of a breast flange and a nipple tunnel;</td><td>The Momcozy S9 Pro includes a breast shield made up of a breast flange and a nipple tunnel.

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Exhibit 14 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Pro Product

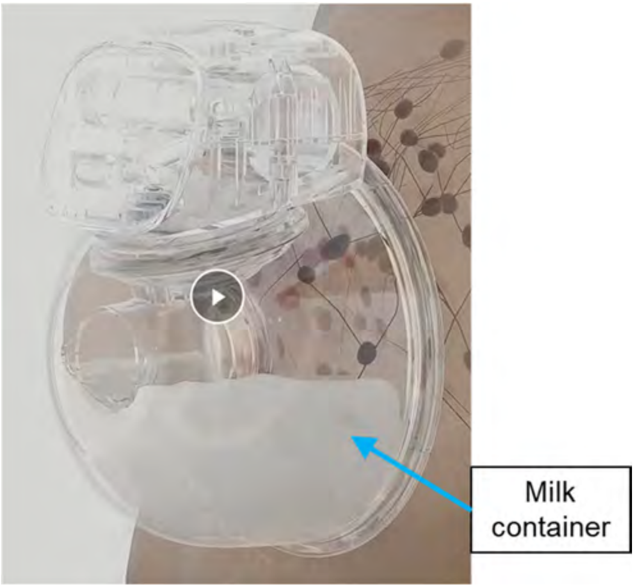
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9 Pro**
		The Momcozy website states that the Momcozy S9 Pro includes a “Default Flange Size: 24mm.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.) As shown above, the breast shield includes a breast flange and a nipple tunnel.
1.4	a milk container that is configured to be attached to and removed from the housing; and	The Momcozy S9 Pro includes a milk container. The Momcozy website states that the Momcozy S9 Pro includes a “Milk Collector (180ml).” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.) 

Exhibit 14 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.	
Claim Language	**Momcozy S9 Pro**
	The Momcozy S9 Pro milk container is configured to be attached to and removed from the housing.  

Exhibit 14 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Pro Product

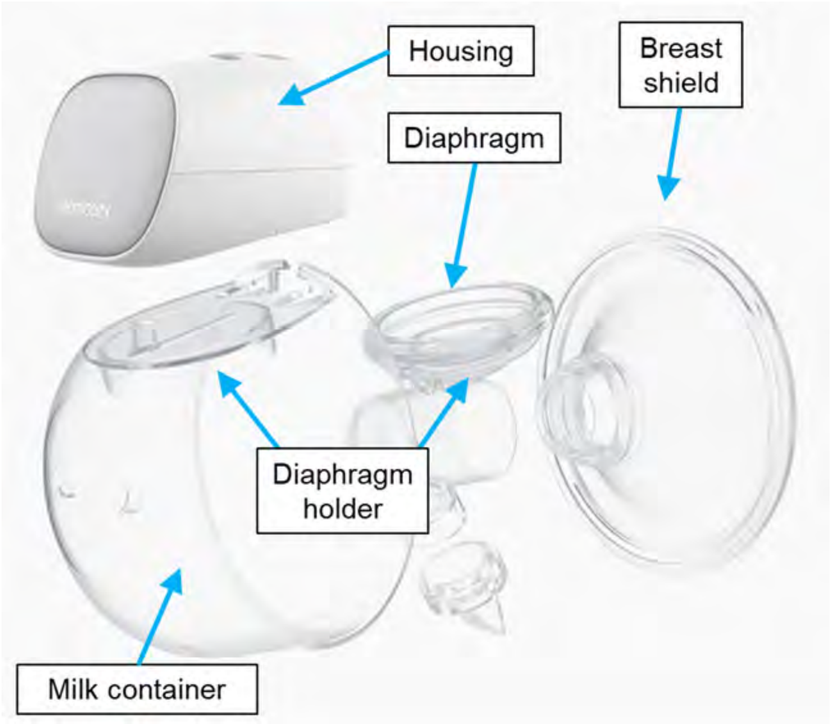
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9 Pro**
1.5	a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing,	The Momcozy S9 Pro includes a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing.  The Momcozy website indicates that the S9 Pro product includes a “Silicone Diaphragm.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.) As shown below, a diaphragm holder forms a recess or cavity above the diaphragm and between an external surface of the housing.

Exhibit 14 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Pro Product

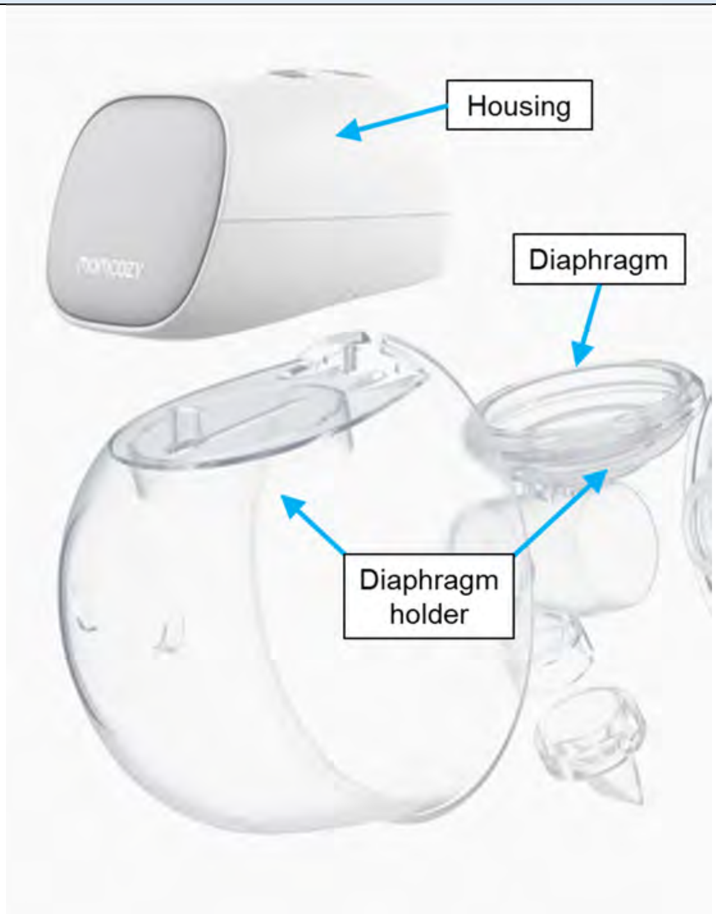
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.		
Claim Language		**Momcozy S9 Pro**
		

Exhibit 14 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
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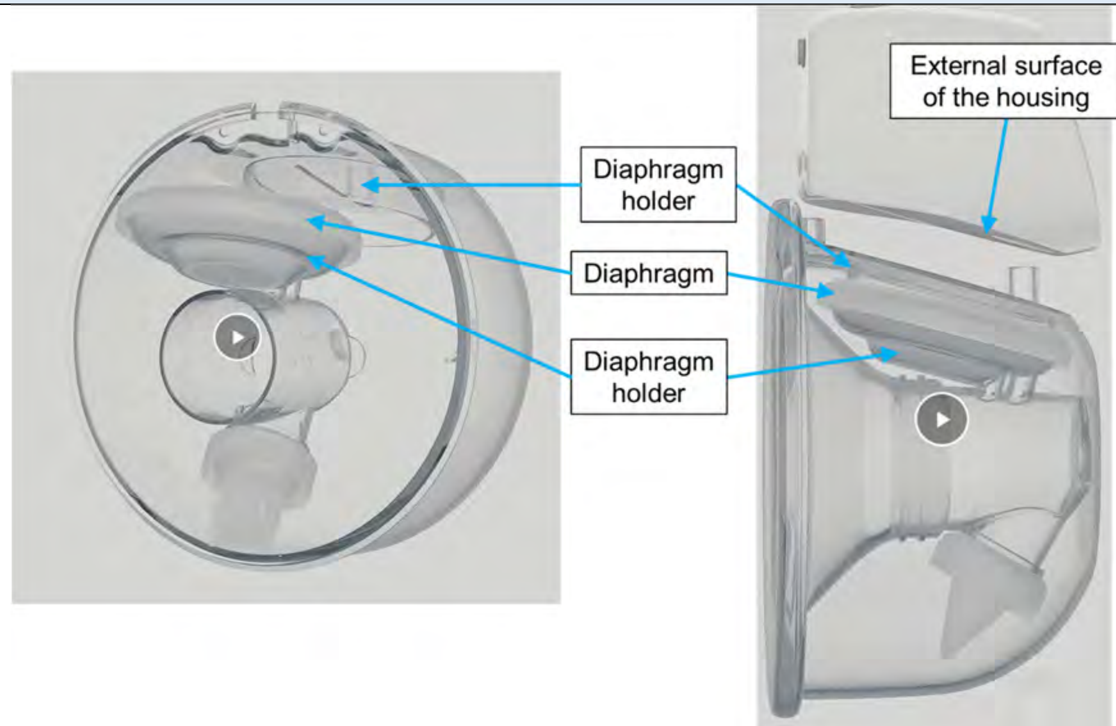
<tr><td></td><td></td><td>
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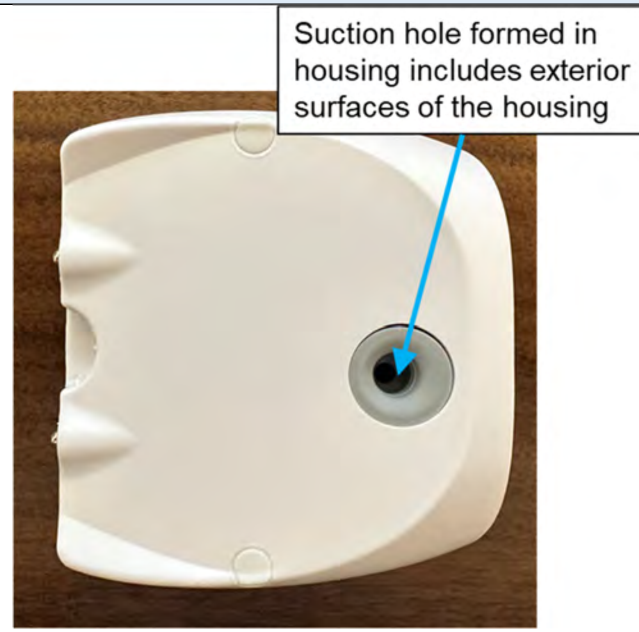
		

Exhibit 14 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Pro Product

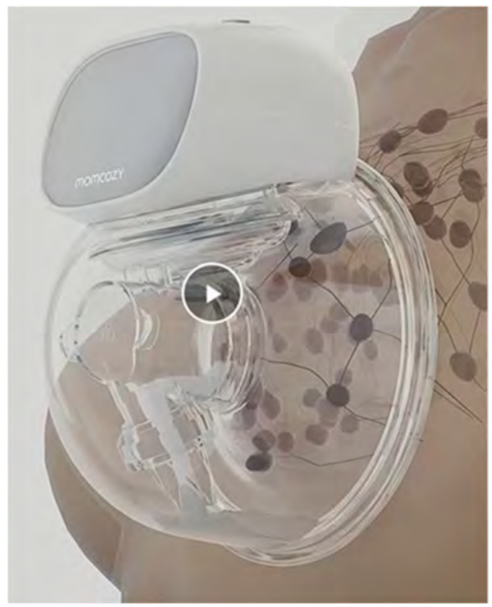
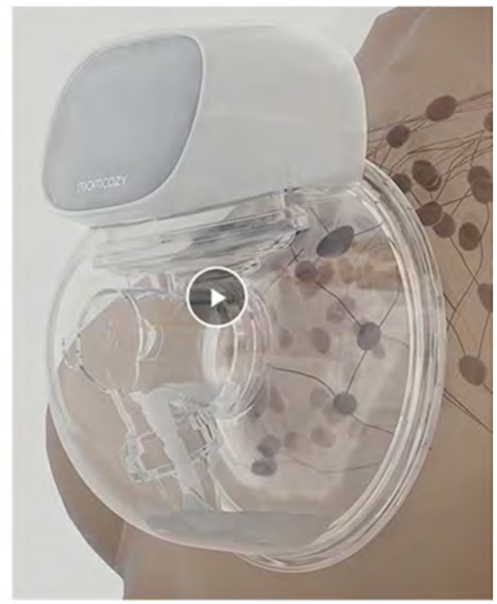
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9 Pro**
1.6	the diaphragm deforming in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.	The Momcozy S9 Pro includes the diaphragm that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. The Momcozy S9 Pro user guide states that the “Momcozy pump has 9 vacuum pressure settings for each mode.” (Momcozy S9 Pro User Guide, p. 12.) As shown in the images below, the diaphragm deforms to create negative air pressure in the nipple tunnel.   (https://www.amazon.com/vdp/000d21f3cc6741eba9f74d3896d39d92?product=B0BXH2PM3Z&ref=cm_sw_em_r_ib_dt_0F7jkWeZZk35u.)

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Exhibit 15

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

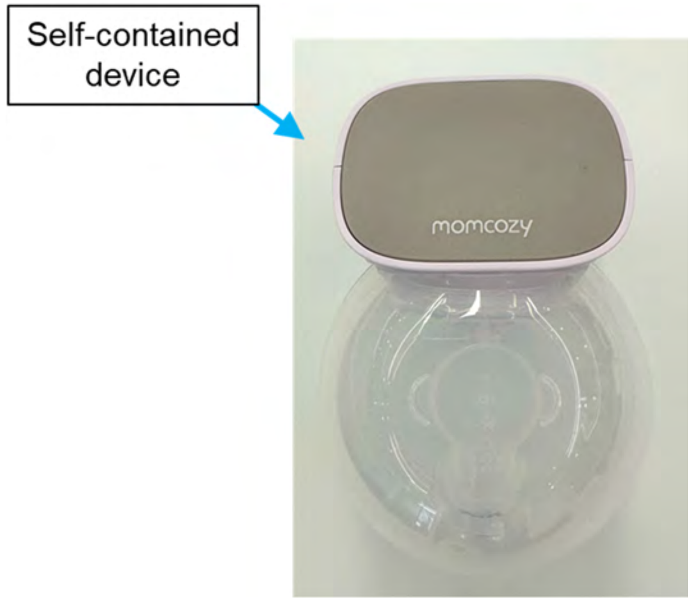
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9**
Claim 1		
1.1	A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:	The Momcozy S9 is a breast pump device. The Momcozy S9 is described as a “2 Mode Wearable Electric Breast Pump.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) The Momcozy S9 is a breast pump device that is configured as a self-contained device, as shown below. 

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

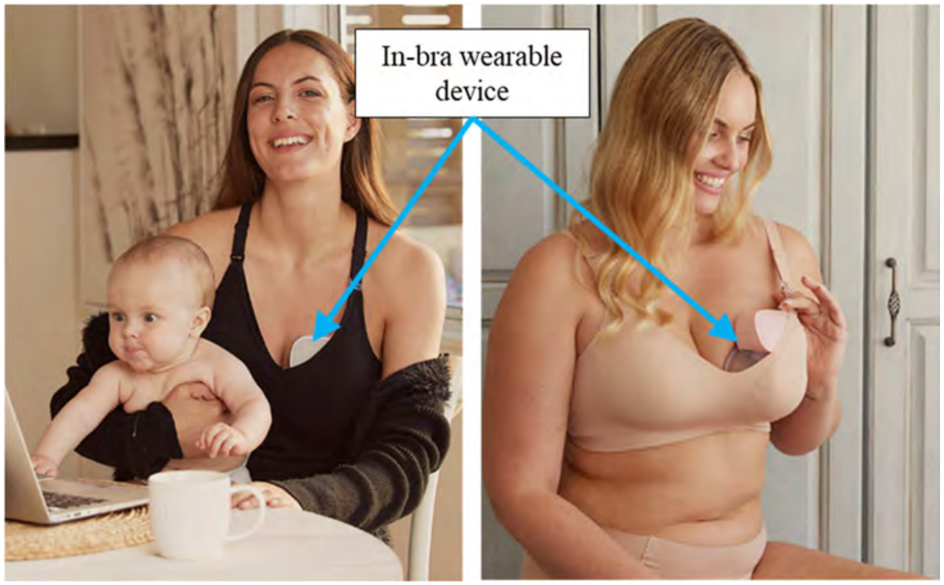
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9**
		The Momcozy S9 is an in-bra wearable device.  (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) As shown above, the Momcozy S9 is in-bra wearable. The Momcozy website explains that the Momcozy S9 is described as “Wearable, Fit Inside Bras.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) The Momcozy S9 “pump is able to fit inside normal nursing bras for the whole day to get rid of ‘finding nursing room’ and ‘repeated bra-offs’ games.” (*Id.*)

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

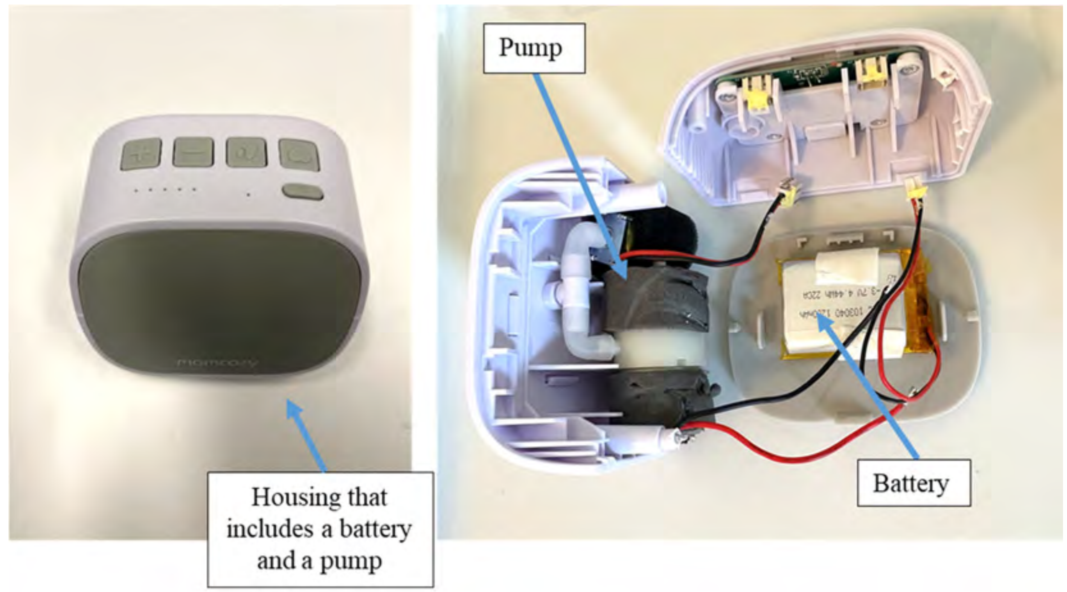
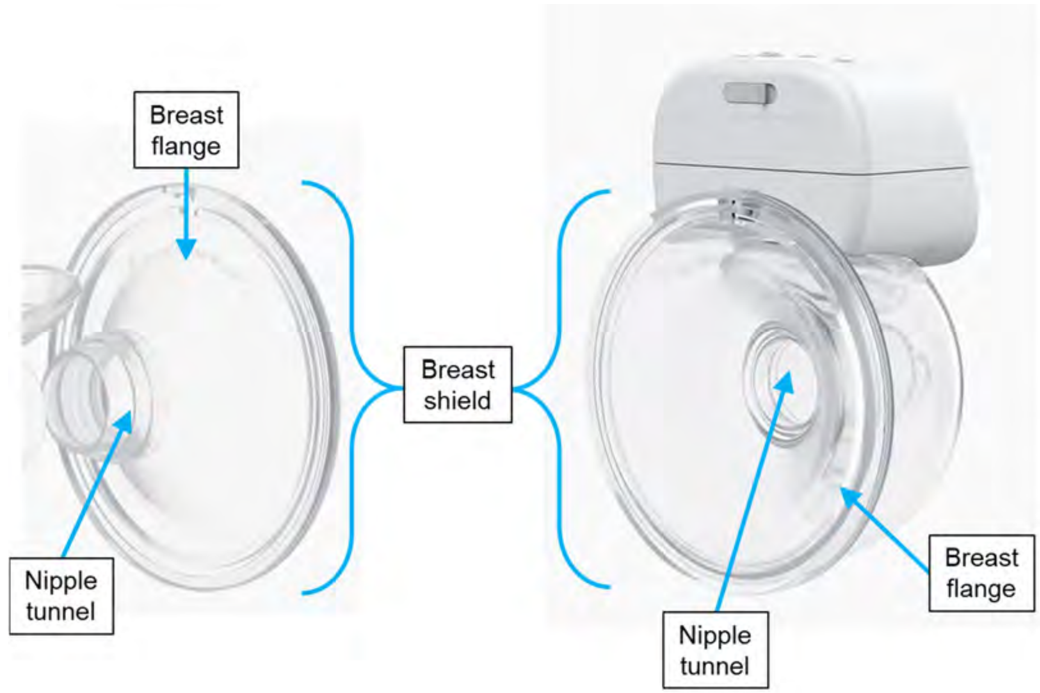
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.		
Claim Language		**Momcozy S9**
1.2	a housing that includes: a battery, and a pump powered by the battery and generating negative air pressure;	The Momcozy S9 includes a housing that includes a battery and a pump.  The Momcozy S9 housing includes a battery. For example, the Momcozy S9 user guide states "[t]his product has a built-in battery," and that they "recommend that you use a certified 5V==1A adapter to charge the battery." (Momcozy, S9 User Manual, p. 2.) The Momcozy S9 housing includes a pump powered by the battery that generates negative air pressure. For example, the Momcozy website advertises that the "wearable hands-free pump can be worn inside a standard nursing bra, so you can pump completely hands-free anytime, anywhere." (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9**
		The Momcozy S9 user guide also identifies the housing as the “pump motor,” as shown as item 4 in the figure below. (Momcozy, S9 User Manual, p. 1.)  The Momcozy S9 pump generates negative air pressure. For example, the Momcozy website states that the S9 breast pump has “5 Adjustable ***Suction*** Levels.” (*Id.*, under “Feature” tab (emphasis added).)

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

<table>
<tr><th colspan="3">The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9</th></tr>
<tr><td>1.3</td><td>a breast shield made up of a breast flange and a nipple tunnel;</td><td>The Momcozy S9 includes a breast shield that includes a breast flange and a nipple tunnel. For example, the Momcozy S9 includes a “Silicone Shield (24 mm).” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)


(https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)</td></tr>
</table>

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

<table>
<tr><th colspan="3">The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>Nipple measurement</th><th>Flange</th></tr>
<tr><td>11-13mm</td><td>17mm</td></tr>
<tr><td>14-16mm</td><td>19mm</td></tr>
<tr><td>17-19mm</td><td>21mm</td></tr>
<tr><td>20-22mm</td><td>24mm</td></tr>
<tr><td>23-25mm</td><td>27mm</td></tr>
</table>
</td></tr>
</table>

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

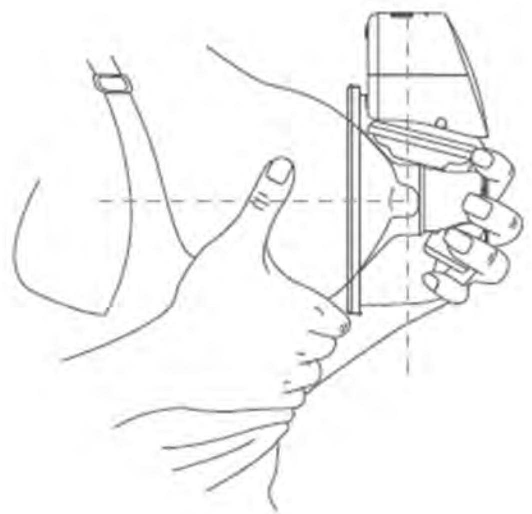
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9**
		 Momcozy, S9 User Manual, p. 1.  Momcozy, S9 User Manual, p. 6.

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

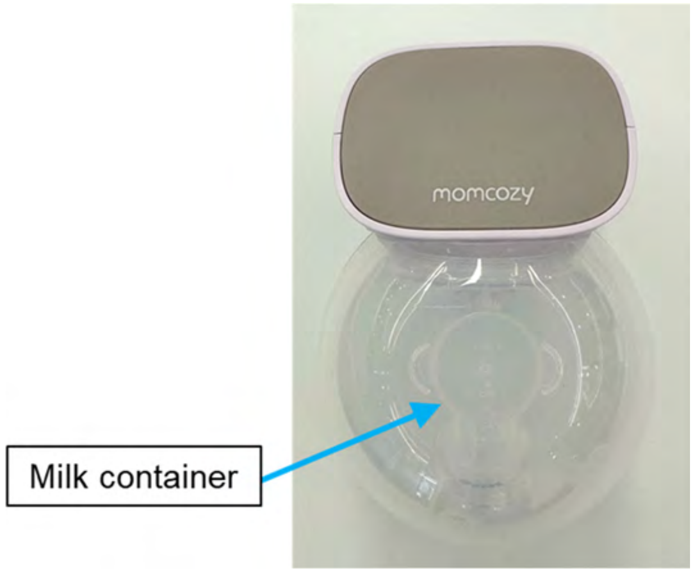
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9**
1.4	a milk container that is configured to be attached to and removed from the housing; and	The Momcozy S9 includes a milk container.  The Momcozy website shows that the S9 product includes a “milk collector (180ml/6oz).” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9**
		The Momcozy S9 milk container is configured to be attached to and removed from the housing.  The S9 user guide illustrates removal and attachment of the housing to the milk container, as shown below. (Momcozy, S9 User Manual, p. 10.)

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

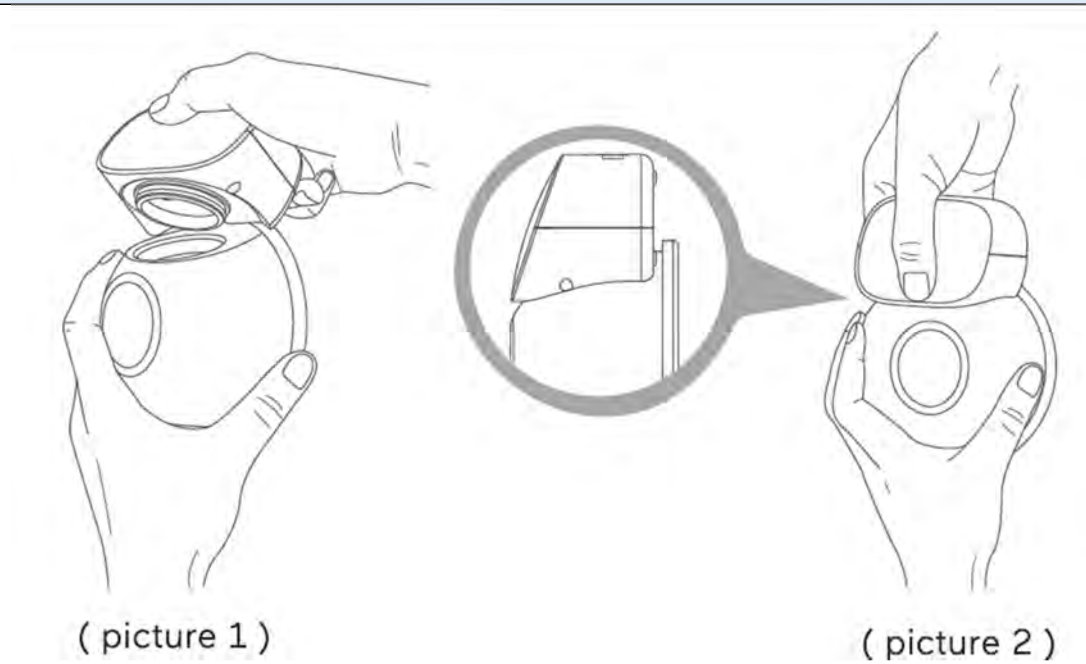
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
Claim Language		**Momcozy S9**
		

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

<table>
<tr><th colspan="3">The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9</th></tr>
<tr><td>1.5</td><td>a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing,</td><td>The Momcozy S9 includes a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing.

The Momcozy website states that the Momcozy S9 product includes a “silicone diaphragm.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9, under “What’s included” tab.)</td></tr>
</table>

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’893 Patent.		
	Claim Language	**Momcozy S9**
		The diaphragm holder forms a recess or cavity at least in part with an external surface of the housing. 

Exhibit 15 – U.S. Patent No. 11,357,893 – Infringement Claim Chart for Momcozy S9 Product

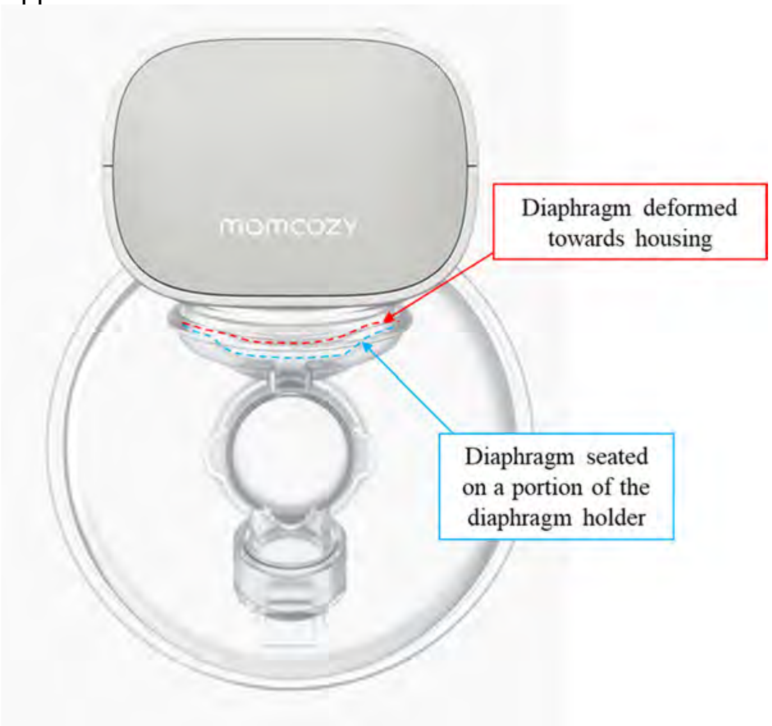
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '893 Patent.		
Claim Language		**Momcozy S9**
1.6	the diaphragm deforming in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.	The Momcozy S9 includes the diaphragm which deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. The Momcozy S9 product is advertised as having "5 Adjustable Suction Levels and 2 Modes." (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) On information and belief, when the pump is operated in the housing, it creates a change in air pressure that deforms the diaphragm to create negative pressure in the nipple tunnel. 

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Exhibit 16

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M1**
Claim 29		
29.P	A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:	The Momcozy M1 is a breast pump device. The Momcozy M1 is described as a “Wearable Breast Pump.” (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) The Momcozy M1 is a breast pump device that is configured as a self-contained device, as shown below. 

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

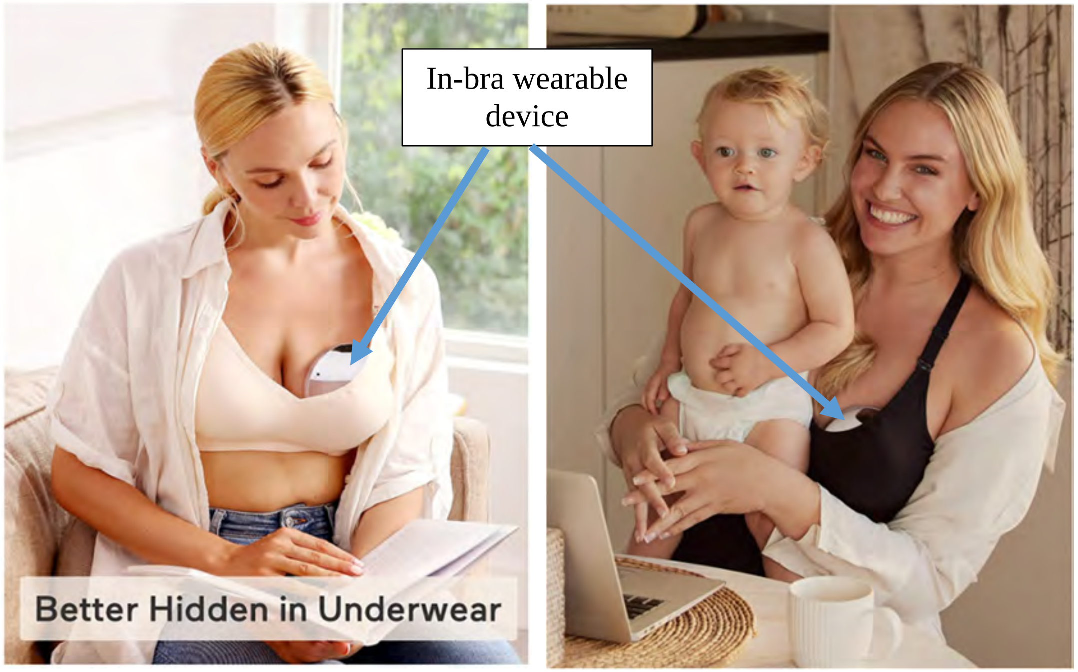
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M1**
		The Momcozy M1 is an in-bra wearable device.  (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) As shown above, the Momcozy M1 fits inside a user’s bra. Momcozy’s Amazon listing describes the Momcozy M1 as “Momcozy Double Wearable Breast Pump M1” that is a “Portable All-in-One Breastfeeding Breast Pump.” (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) Momcozy’s Amazon listing indicates that the Momcozy M1 includes “All-in-one Design - Electric Breast Pump M1 is completely invisible when wearing underwear.” (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) Momcozy further advertises that the “M1 is fit for nursing bras.” (*Id.*)

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy M1**
		 Momcozy M1 Video on Amazon.com (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y, at 2 seconds.)
29.1	a self-contained, in-bra wearable device comprising:	*See* 29.P.

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

<table>
<tr><th colspan="3">The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M1</th></tr>
<tr><td>29.2</td><td>a housing that includes:

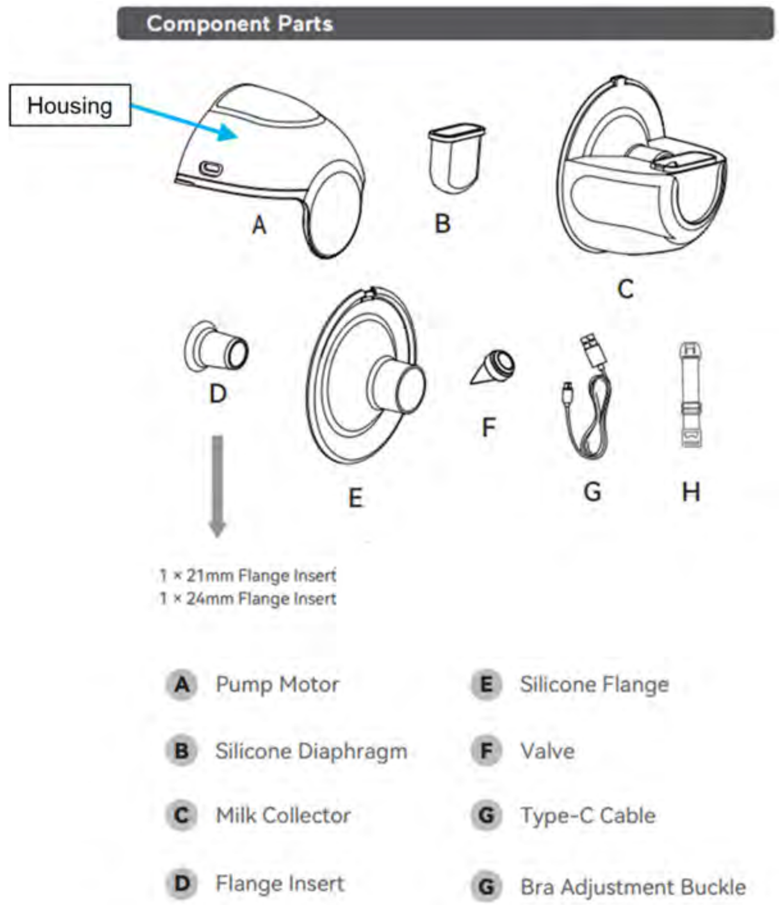
a rechargeable battery,

a power charging circuit for controlling charging of the rechargeable battery,

control electronics powered by the rechargeable battery,

a pump powered by the rechargeable battery and configured to generate negative air pressure, and

a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery;</td><td>The Momcozy M1 includes a pump housing that includes a rechargeable battery, a power charging circuit, control electronics, and a USB charging socket.



(https://m.media-amazon.com/images/I/A19ypwxs58L.pdf.)</td></tr>
</table>

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M1**
		The Momcozy M1 pump housing includes a rechargeable battery. For example, Momcozy M1 includes a “1200mAh capacity battery, Type-C charging speed is faster, can be used about 90-150 mins / 3-5 times when fully charged.” (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) On information and belief, the Momcozy M1 pump housing includes a power charging circuit for controlling charging of the rechargeable battery and control electronics powered by the rechargeable battery because the Momcozy M1 is rechargeable, it has buttons that change the operation of the pump, and it is “All-in-one Design - Electric Breast Pump M1.” (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) The Momcozy M1 pump housing includes a pump powered by the rechargeable battery and configured to generate negative air pressure. The Momcozy Amazon listing states that the “Momcozy wearable breast pump M1 has 3 modes and 9 suction levels.” (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) The Momcozy M1 pump housing includes a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery.

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

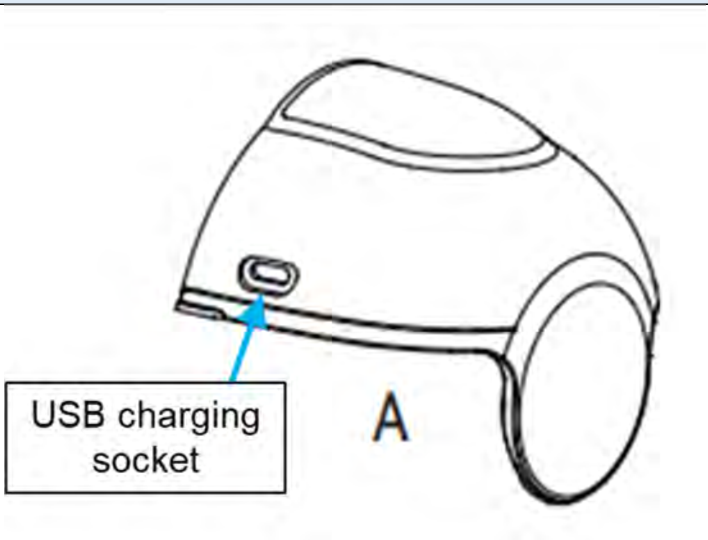
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M1**
		

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy M1**
29.3	a breast shield made up of a breast flange and a nipple tunnel;	The Momcozy M1 includes a breast shield that includes a breast flange and a nipple tunnel.  The Momcozy website indicates that the Momcozy M1 device includes a breast shield with sizes of "21/24/27mm." (https://www.momcozy.net/products/double-all-in-one-wearable-breast-pump-m1.)

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

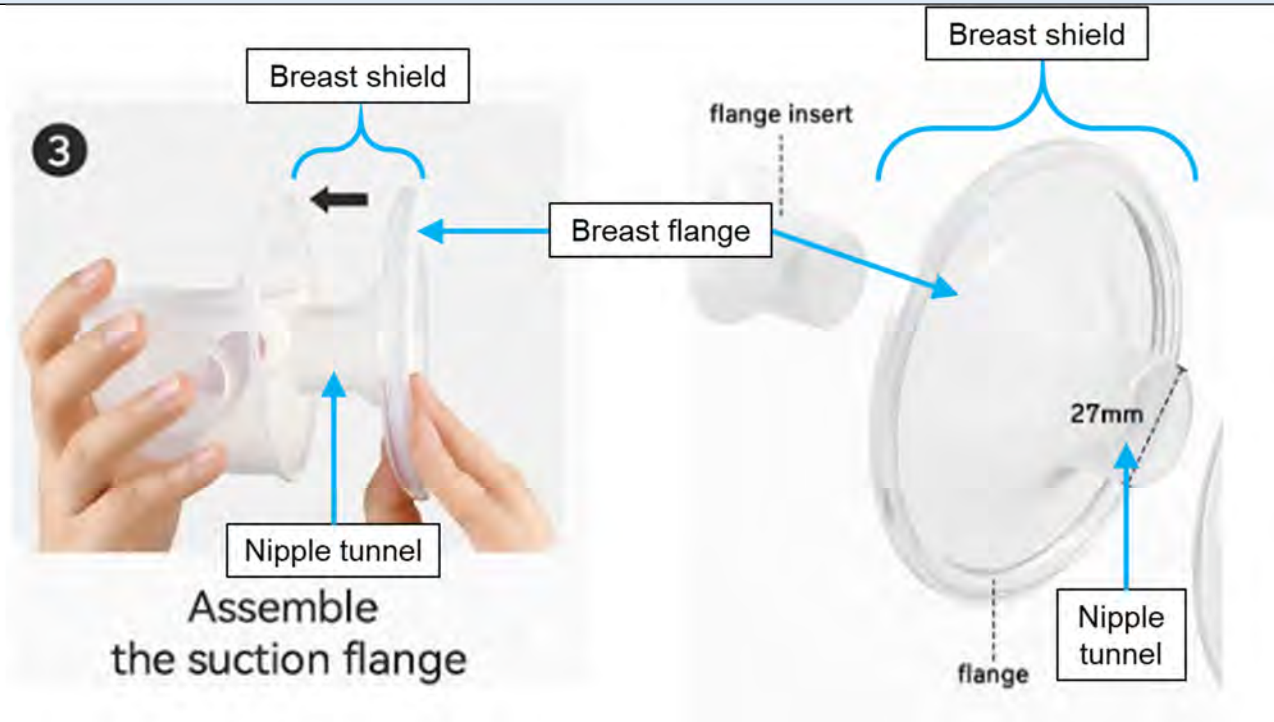
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
	Claim Language	**Momcozy M1**
		 Momcozy Breast shield images (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.)

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		Momcozy M1
29.4	a milk container that is configured to be attached to and removed from the housing; and	The Momcozy M1 includes a milk container.  The Momcozy website indicates that the M1 has a "Milk Collector (150ml)" (https://www.momcozy.net/products/double-all-in-one-wearable-breast-pump-m1.) The Momcozy M1 milk container is configured to be attached to and removed from the housing.

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
	Claim Language	**Momcozy M1**
		 Momcozy M1 Device showing milk container attached to and removed from the housing Momcozy provides a "quick installation" guide in the images available on Amazon.com that shows how to attach the housing to the milk container (shown below).

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy M1**
		 Quick installation of the Momcozy M1 device (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.)

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

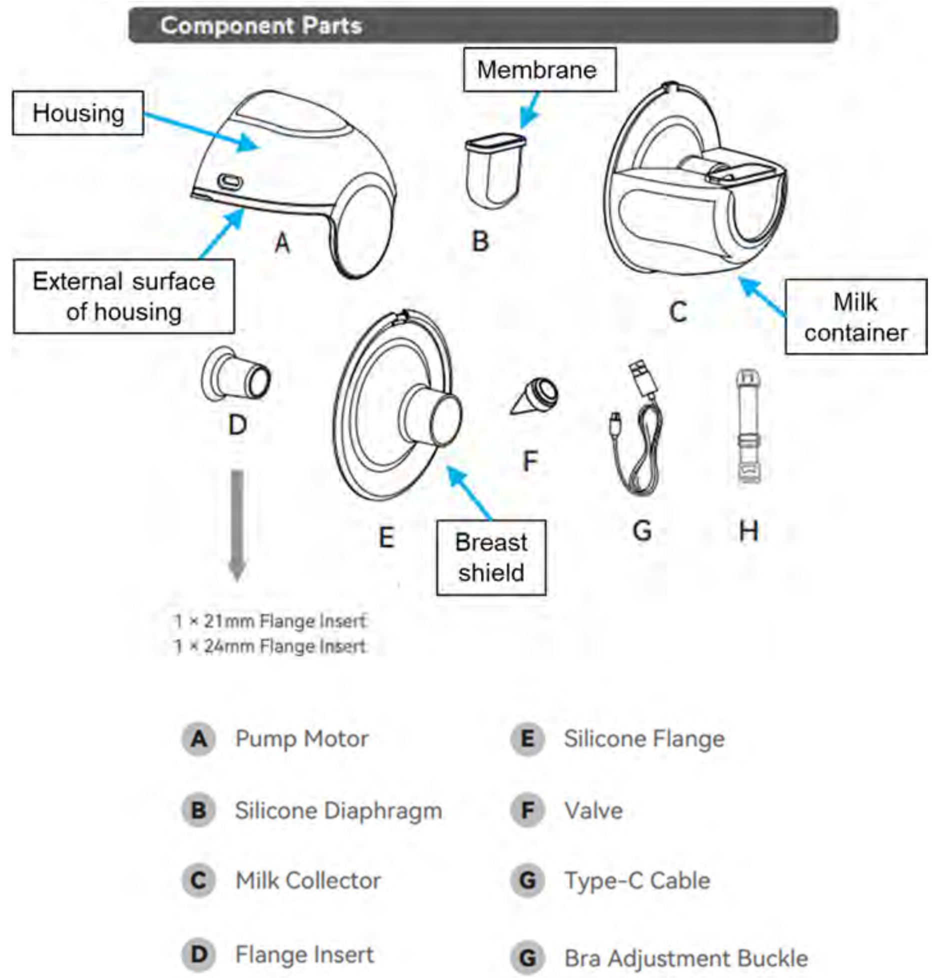
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy M1**
29.5	a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing,	The Momcozy M1 includes a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing. 

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

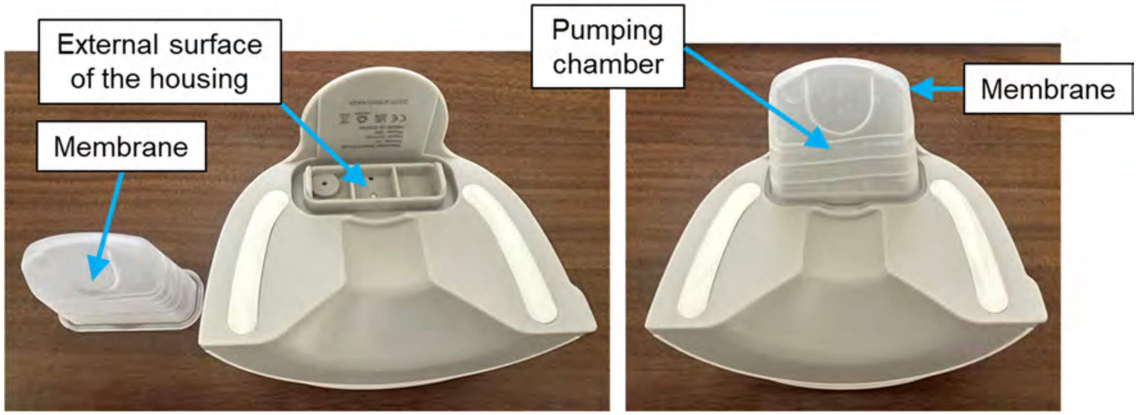
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
	Claim Language	**Momcozy M1**
		The Momcozy M1 includes a "Silicone Diaphragm," as shown above. (https://m.media-amazon.com/images/I/A19ypwxs58L.pdf.) The diaphragm couples to the housing to define a pumping chamber at least in part with an external surface of the housing. (https://www.amazon.com/Momcozy-Wearable-M1-Hands-Free-Breastfeeding/dp/B09X1GGP5Y.) When the Momcozy M1 breast pump is assembled, the open end of the silicone diaphragm is pressed against an external surface of the housing. Accordingly, a pumping chamber is defined with an external surface of the housing. 

Exhibit 16 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M1 Product

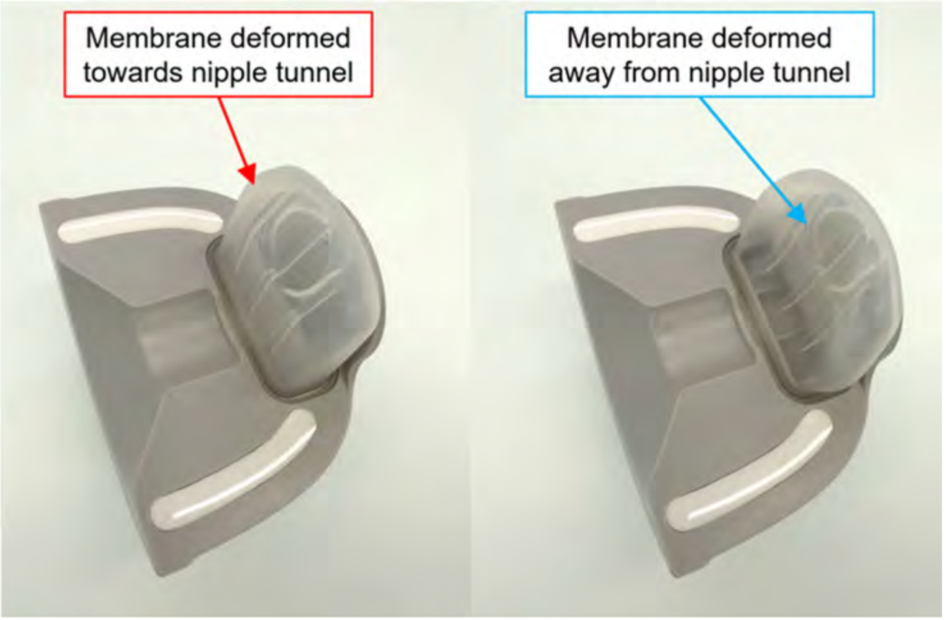
The Momcozy M1 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M1**
29.6	the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.	The Momcozy website advertises “9 suction levels” for the Momcozy M1 device. (https://www.momcozy.net/products/double-all-in-one-wearable-breast-pump-m1.) When the pump is operated in the housing, it creates a change in air pressure that deforms the membrane, so that the membrane oscillates towards and away from the nipple tunnel. The movement of the membrane causes a negative pressure in the nipple tunnel allowing for milk expression. The deformation of the membrane is illustratively shown below: 

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Exhibit 17

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M5**
Claim 29		
29.P	A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:	The Momcozy M5 is a breast pump device. The Momcozy M5 is described as an “All-in-one M5 Wearable Breast Pump.” (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump?variant=42648706777286.) The Momcozy M5 is a breast pump device that is configured as a self-contained device, as shown below. 

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M5**
		The Momcozy M5 is an in-bra wearable device.  (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.) As shown above, the Momcozy M5 fits inside a user’s bra. Momcozy’s website describes the Momcozy M5 as an “All-in-one M5 Wearable Breast Pump.” (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.) Momcozy provides a “how to use Momcozy M5 Wearable Breast Pump” video on the Momcozy website and is further provided on youtube.com, which instructs a

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

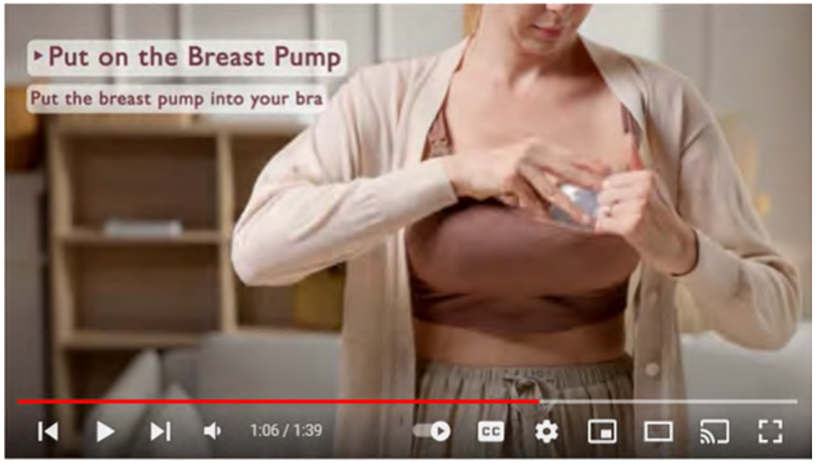
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy M5**
		user to "[p]ut the breast pump into your bra." (https://youtu.be/xNy5KCRf7Uo, at 64 seconds; screen shot reproduced below.) 
29.1	a self-contained, in-bra wearable device comprising:	*See* 29.P.

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

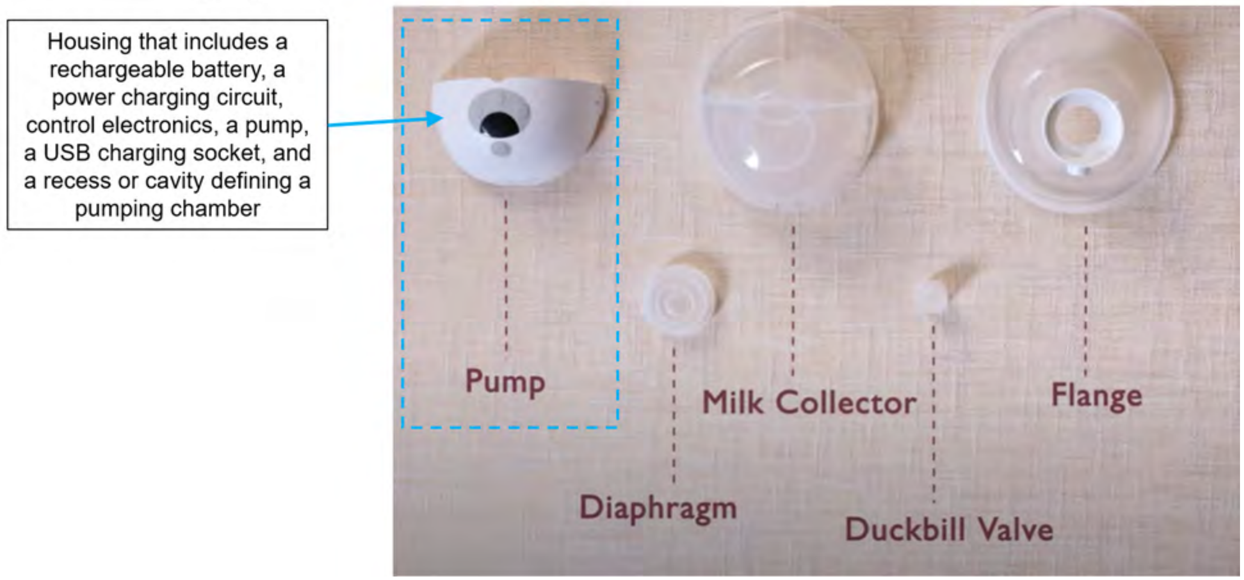
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M5**
29.2	a housing that includes: a rechargeable battery, a power charging circuit for controlling charging of the rechargeable battery, control electronics powered by the rechargeable battery, a pump powered by the rechargeable battery and configured to generate negative air pressure, and a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery;	The Momcozy M5 includes a pump housing that includes a rechargeable battery, a power charging circuit, control electronics, a pump, and a USB charging socket.  Momcozy M5 “How to use” video (https://youtu.be/xNy5KCRf7Uo, at 32 seconds.) The Momcozy M5 pump housing includes a rechargeable battery. For example, Momcozy M5 includes a USB-C port in the housing to charge the battery and gives a “charge time [of] about 2 hours, power adapter must be 5V-1A.” (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump)

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.	
Claim Language	**Momcozy M5**
	 Momcozy M5 "How to use" video (https://youtu.be/xNy5KCRf7Uo, at 6 seconds.) On information and belief, the Momcozy M5 pump housing includes a power charging circuit for controlling charging of the rechargeable battery and control electronics powered by the rechargeable battery because the Momcozy M5 is rechargeable, it has buttons that change the operation of the pump, and it is an "[a]ll-in-one" device. (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.) The Momcozy M5 pump housing includes a pump powered by the rechargeable battery and configured to generate negative air pressure. For example, the Momcozy website advertises a "[p]ainless to pump like a baby mouth," with "9 adjustable suction levels." (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.) Momcozy shows an illustration of the pump within the housing in the "Momcozy Muse 5" video, reproduced below.

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

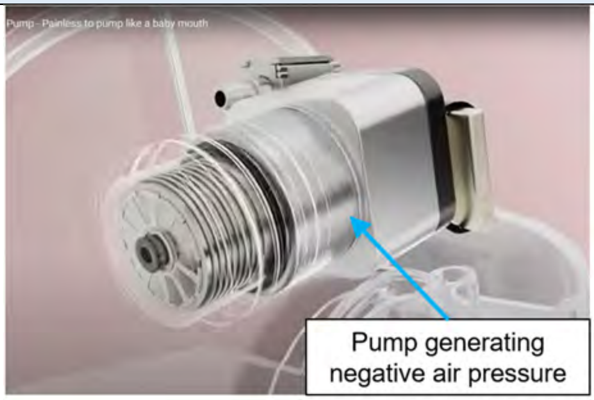
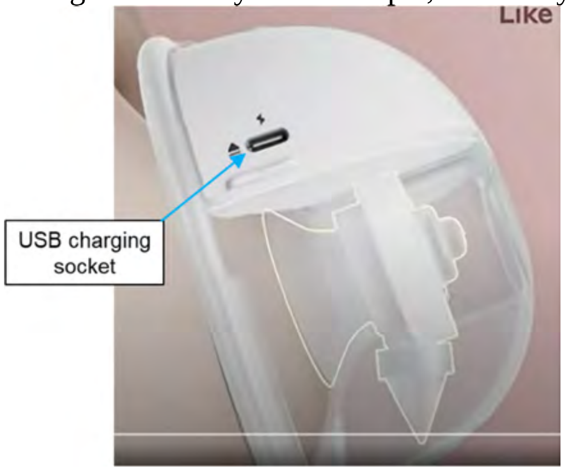
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M5**
		 Illustration of Momcozy M5 pump motor (https://youtu.be/roJ3nLLVTgM, at 8 seconds.) The Momcozy M5 includes a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery. For example, Momcozy M5 includes a USB port. 

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M5**
29.3	a breast shield made up of a breast flange and a nipple tunnel;	The Momcozy M5 includes a breast shield that includes a breast flange and a nipple tunnel. 

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

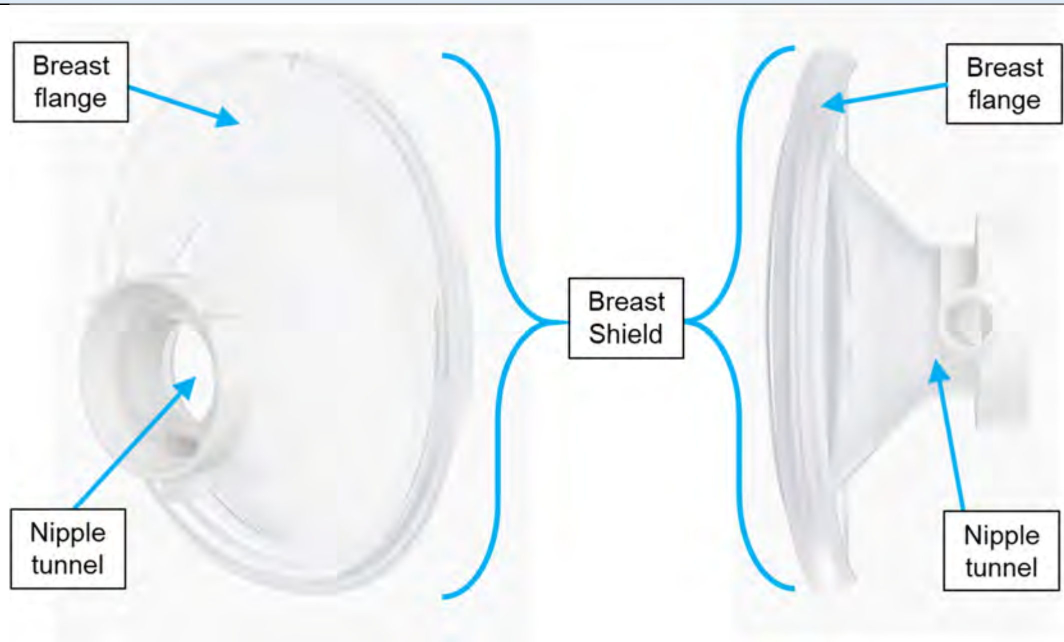
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M5**
		 (https://momcozy.com/products/m5-breast-pump-replacement-parts.)

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

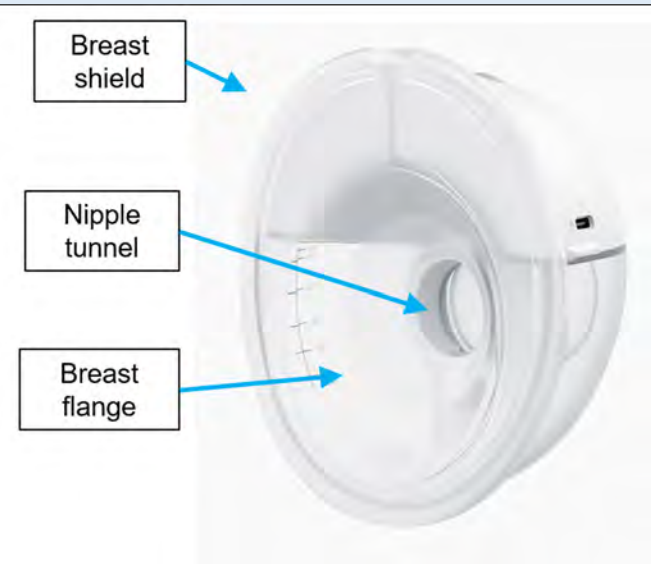
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy M5**
		 The Momcozy website indicates that the M5 product includes a breast shield with "flange size: 24mm/27mm," with the website further detailing a "105° flange slope." (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.)

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

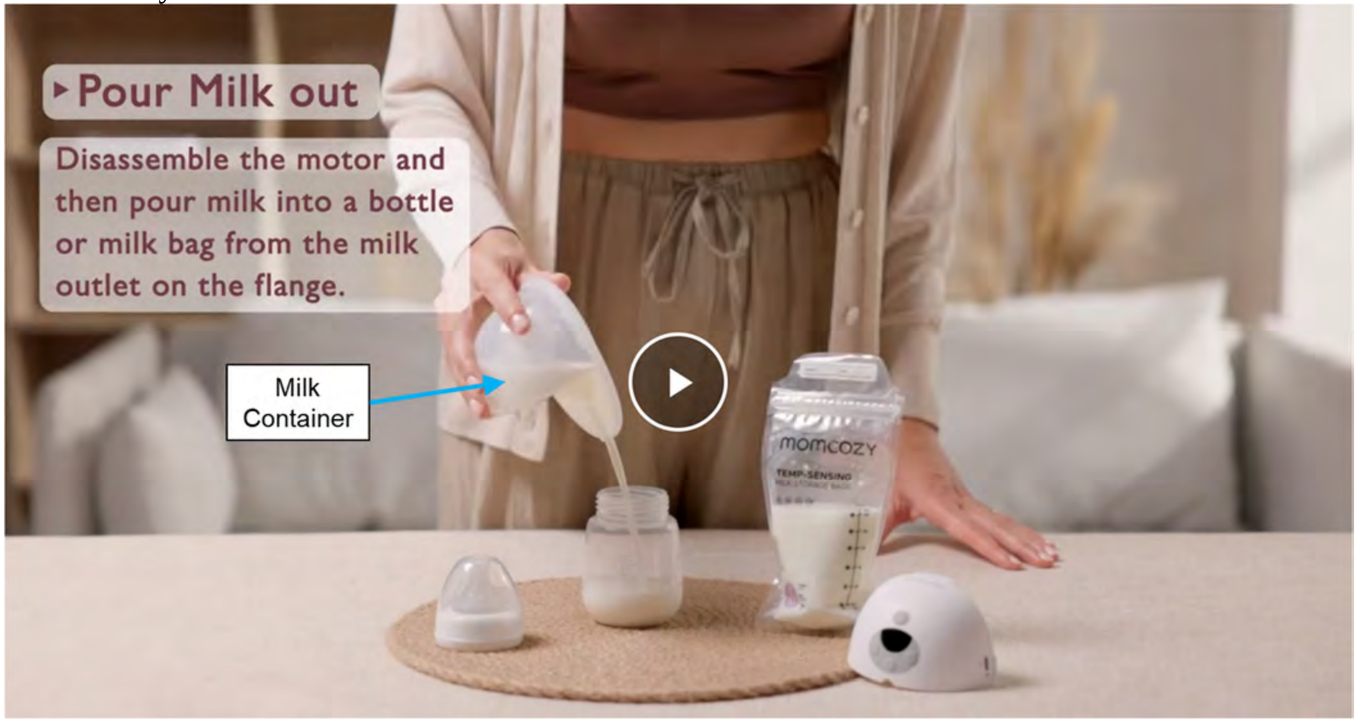
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M5**
29.4	a milk container that is configured to be attached to and removed from the housing; and	The Momcozy M5 includes a milk container.  (https://www.amazon.com/Momcozy-Wearable-Double-Sealed-Electric-Portable/dp/B0B74SJ9SB?th=1.) (Videos “Momcozy M5 Wearable Breast Pump Use Guide, at 1:34). The Momcozy website states that the M5 has a “bottle capacity : >120ml.” (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.)

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.	
Claim Language	**Momcozy M5**
	The milk container is configured to be attached to and removed from the housing.  Momcozy M5 "How to use" video (https://youtu.be/xNy5KCRf7Uo, at 56-60 seconds.)

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy M5**
		The M5 installation guidelines and user manual also illustrates removal and assembly of the housing to the milk container. (Momcozy, M5 User Manual, pp. 9, 13; *See also* Momcozy, M5 Installation Guidelines, p. 1.) 

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

<table>
<tr><th colspan="3">The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy M5</th></tr>
<tr><td>29.5</td><td>a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing,</td><td>

As shown below, Momcozy instructs a user to “[s]nap the diaphragm onto the milk container,” referring to the membrane in the annotated picture above. (https://youtu.be/xNy5KCRf7Uo, at 36-42 seconds; screen shot reproduced below.) The edge of the diaphragm housing is circular and matches the size of the membrane. The membrane includes a lip around the edge that seats on the rim of the diaphragm housing. The membrane is supported by another holder that is attached to the nipple tunnel.</td></tr>
</table>

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M5**
		 As shown above and below, the membrane defines the pumping chamber at least in part with an external surface of the housing.

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

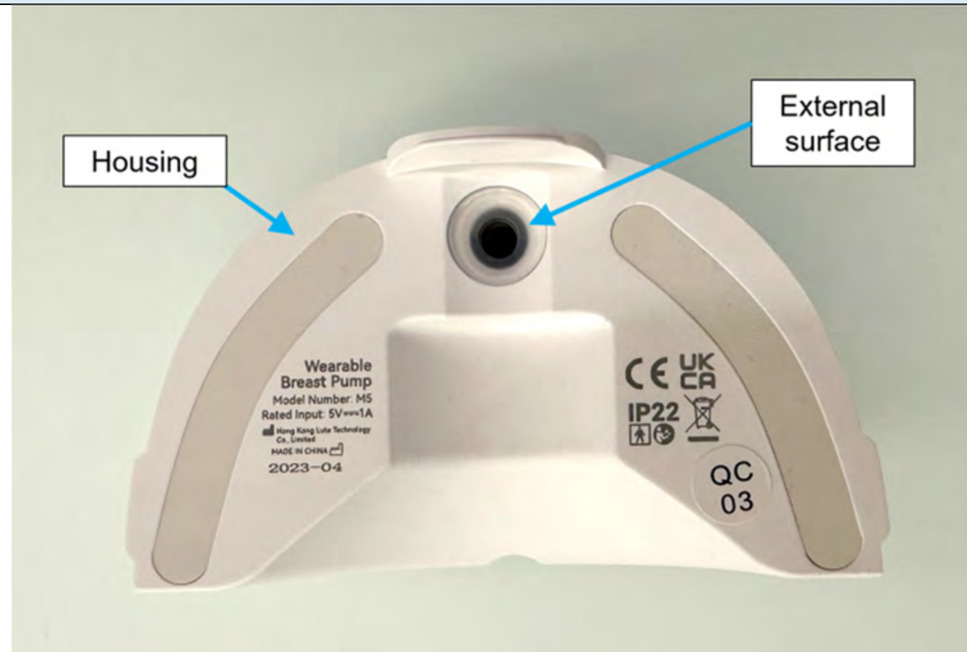
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.	
Claim Language	**Momcozy M5**
	

Exhibit 17 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy M5 Product

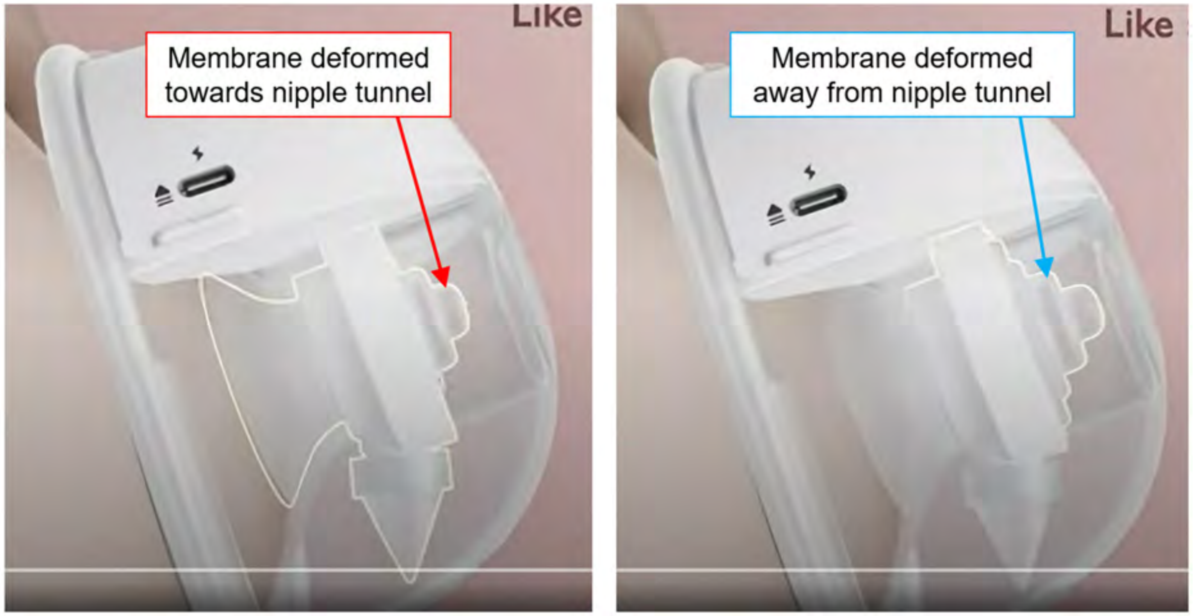
The Momcozy M5 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy M5**
29.6	the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.	The Momcozy M5 includes the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. The Momcozy website advertises “9 adjustable suction levels” for the M5 device. (https://momcozy.com/products/all-in-one-m5-wearable-breast-pump-painless-to-pump.) The “Momcozy Muse 5” video, still images reproduced below, shows the deforming movement of the membrane that creates negative air pressure in the nipple tunnel.  Illustrative video of Momcozy M5 deforming membrane (https://youtu.be/roJ3nLLVTgM, at 2-7 seconds.)

Exhibit 18

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S12 Pro**
Claim 29		
29.P	A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:	The Momcozy S12 Pro is a breast pump device. The Momcozy website states that the Momcozy S12 Pro is a “Wearable Breast Pump.” (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.) The Momcozy S12 Pro is a breast pump device that is configured as a self-contained device, as shown below. 

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S12 Pro**
		The Momcozy S12 Pro is an in-bra wearable device.  (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.) The website states that “this bra-fit wearable breast pump allows for ultimate free pumping on the go for multitasking and body motion to exercise, which is a shortcut for moms to get the balance of nursing babies and regain normal lives.” (*Id.*) Additionally, the Momcozy website discloses that “[Momcozy’s] hands-free breast pump is designed to be worn with your standard nursing bra.” (*Id.*)
29.1	a self-contained, in-bra wearable device comprising:	*See* 29.P.

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

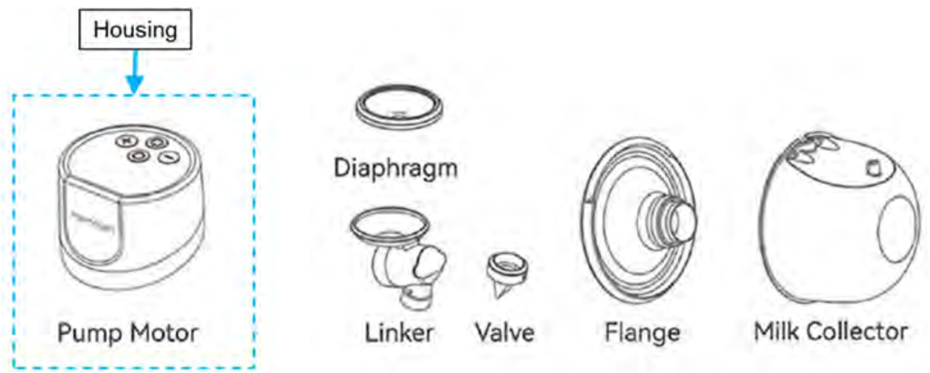
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S12 Pro**
29.2	a housing that includes: a rechargeable battery, a power charging circuit for controlling charging of the rechargeable battery, control electronics powered by the rechargeable battery, a pump powered by the rechargeable battery and configured to generate negative air pressure, and a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery;	The Momcozy S12 Pro includes a housing that includes a rechargeable battery, a power charging circuit, control electronics, and a USB charging socket.  Momcozy S12 Pro Quick guide, p. 2 The Momcozy S12 Pro housing includes a rechargeable battery. For example, the Momcozy S12 Pro user guide states that “[w]hen charging, the battery indicator lights up one by one, displaying increasing battery percentage from 25%, 50%, 75%, to 100%.” (Momcozy S12 Pro User Guide, p. 13.) On information and belief, the Momcozy S12 Pro housing includes a power charging circuit for controlling charging of the rechargeable battery and control electronics powered by the rechargeable battery because the Momcozy S12 Pro is rechargeable and it has buttons that change the operation of the pump. (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.) The Momcozy S12 Pro housing includes a pump powered by the rechargeable battery and configured to generate negative air pressure. The Momcozy S12 Pro user guide also identifies the housing has the “pump motor,” and states that “[t[he breast pump has 9 suction levels to choose from.” (Momcozy, S12 Pro User Manual, pp. 3, 5, 7.)

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

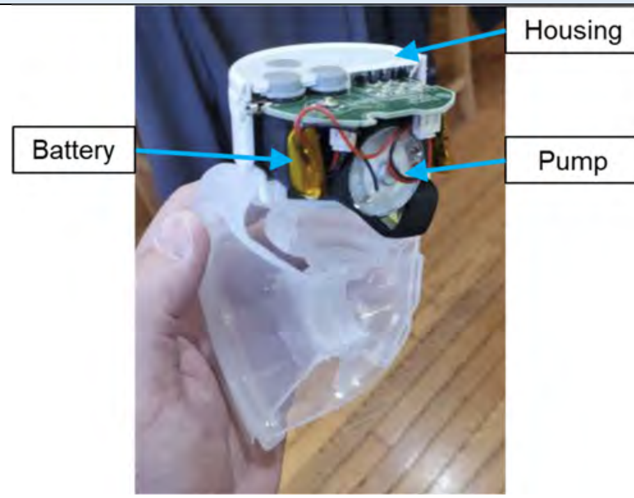
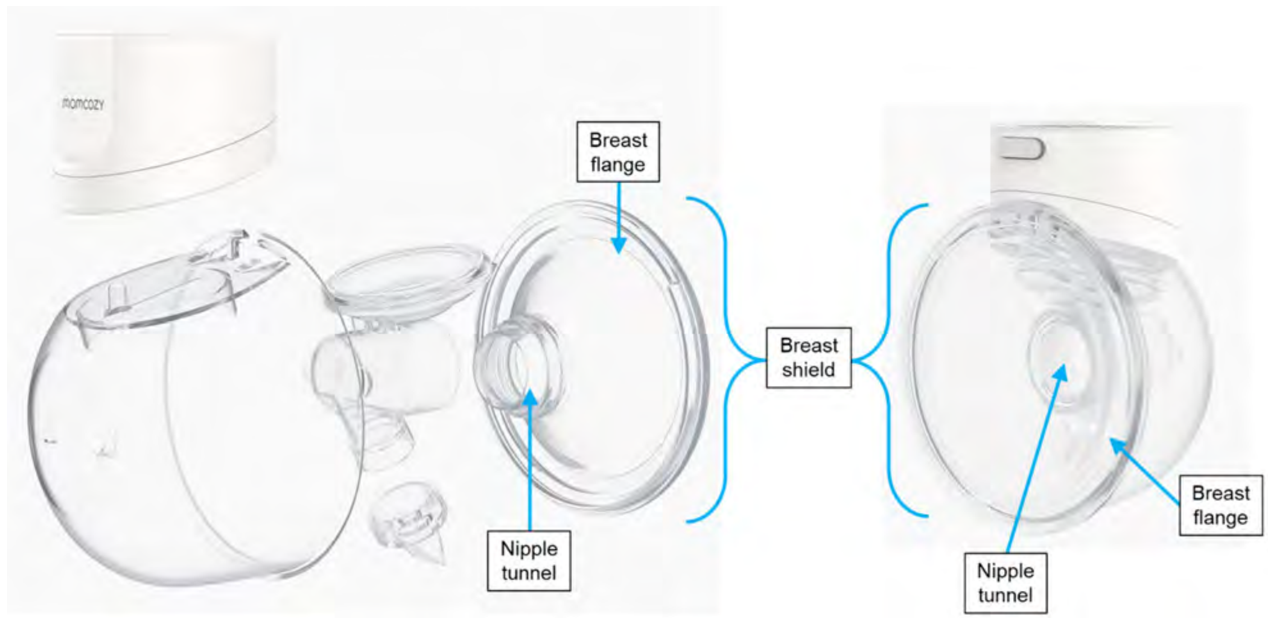
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
	Claim Language	**Momcozy S12 Pro**
		 Momcozy S12 Pro internal components. The Momcozy S12 Pro housing includes a USB charging socket. As shown below, the Momcozy S12 Pro includes a socket for receiving a USB cable. The Momcozy website also states that the “[c]harging port” is “Type-C (Compatible with 5V 1A adapter)” referring to USB Type-C. (*Id.*) The charging port is shown below:  (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.)

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td>29.3</td><td>a breast shield made up of a breast flange and a nipple tunnel;</td><td>The Momcozy S12 Pro includes a breast shield made up of a breast flange and a nipple tunnel.


(https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.)

The Momcozy website indicates that the S12 Pro product includes a “silicone flange (24 mm).” (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump?variant=42641714741446.)</td></tr>
<tr><td>29.4</td><td>a milk container that is configured to be attached to and removed from the housing; and</td><td>The Momcozy S12 Pro includes a milk container that is configured to be attached to and removed from the housing. The Momcozy website clarifies that the S12 Pro product includes a “milk collector (180ml).” (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump?variant=42641714741446.)</td></tr>
</table>

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td></td><td></td><td>

(https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.)</td></tr>
</table>

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S12 Pro**
		 The Momcozy S12 Pro Quick Guide and User Guide also illustrates removal and assembly of the housing to the milk container. (Momcozy, S12 Pro Quick guide, p. 1; *See also* Momcozy, S12 Pro User Manual, pp. 9, 13.)

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

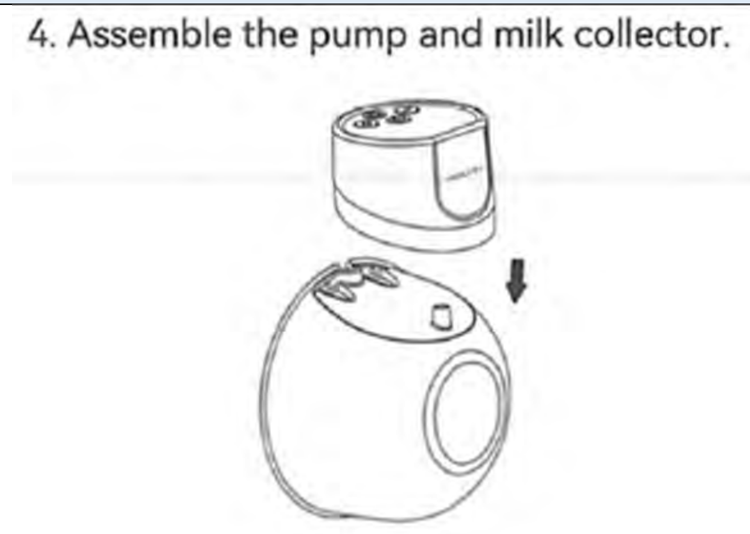
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.	
Claim Language	**Momcozy S12 Pro**
	

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td>29.5</td><td>a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing,</td><td>The Momcozy S12 Pro includes a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing.

As shown below, the Momcozy S12 Pro includes a membrane.

(https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.)

The Momcozy website indicates that the S12 Pro product includes a “silicone diaphragm.” (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump?variant=42641714741446)

As shown below, the membrane is seated on a diaphragm holder that is fixed to an external surface of the housing to define a pumping chamber. The S12 Pro integrates the pumping chamber into the milk</td></tr>
</table>

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

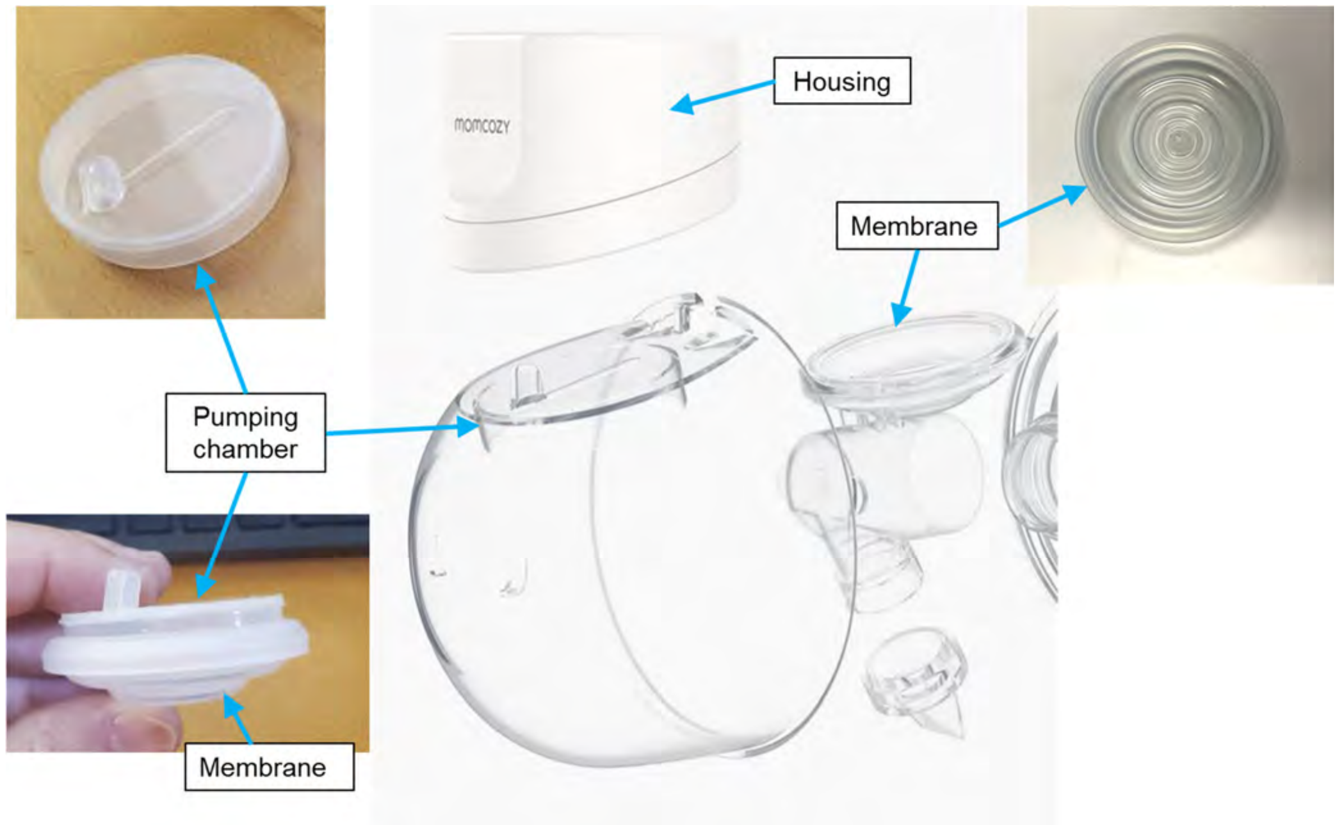
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S12 Pro**
		container, but for clarity, the picture below shows the structure surrounding the pumping chamber as a single component with the milk container removed. 

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

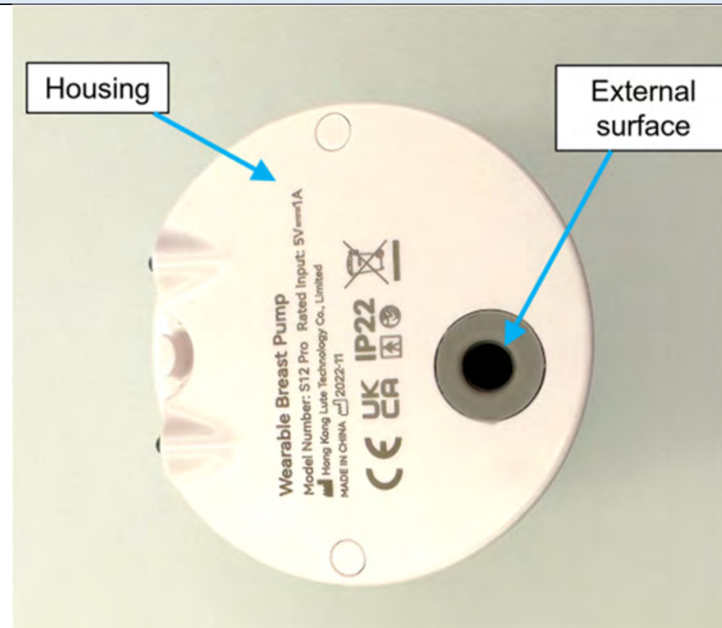
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.	
Claim Language	**Momcozy S12 Pro**
	

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

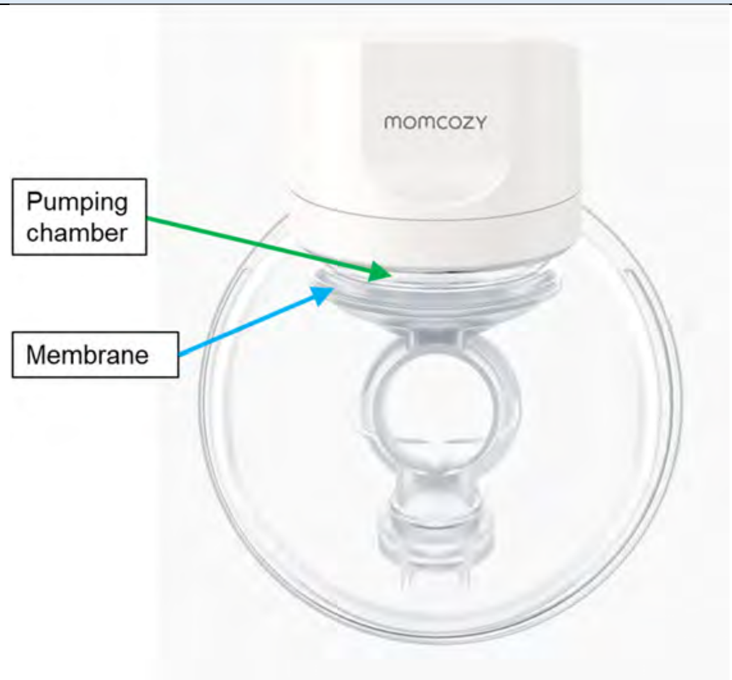
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S12 Pro**
		

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

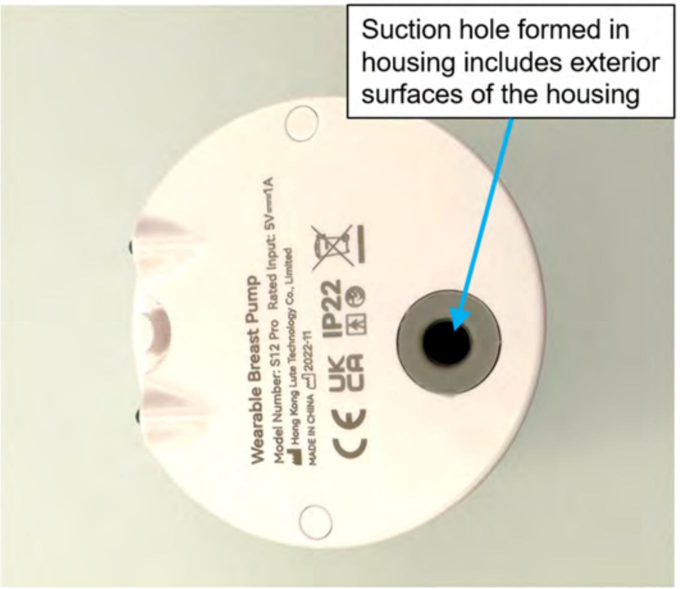
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S12 Pro**
		

Exhibit 18 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S12 Pro**
29.6	the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.	The Momcozy S12 Pro includes the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. The Momcozy S12 Pro User Guide also identifies that “[t[he breast pump has 9 suction levels to choose from.” (Momcozy, S12 Pro User Manual, p. 5.) On information and belief, when the pump is operated in the housing, it creates a change in air pressure that deforms the membrane to create negative pressure in the nipple tunnel. 

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Exhibit 19

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S12**
Claim 29		
29.P	A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:	The Momcozy S12 is a breast pump device. The Momcozy S12 is described as “9 Levels Wearable Electric Breast Pump - S12.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The Momcozy S12 is a breast pump device that is configured as a self-contained device, as shown below. 

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

<table>
<tr><th colspan="3">The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12</th></tr>
<tr><td></td><td></td><td>The Momcozy S12 is an in-bra wearable device.


(https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

The Momcozy S12 is described as a “Wearable Breast Pump.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The Momcozy S12 can “[f]it for any standard nursing bra.” (Id.)</td></tr>
<tr><td>29.1</td><td>a self-contained, in-bra wearable device comprising:</td><td>See 29.P.</td></tr>
</table>

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

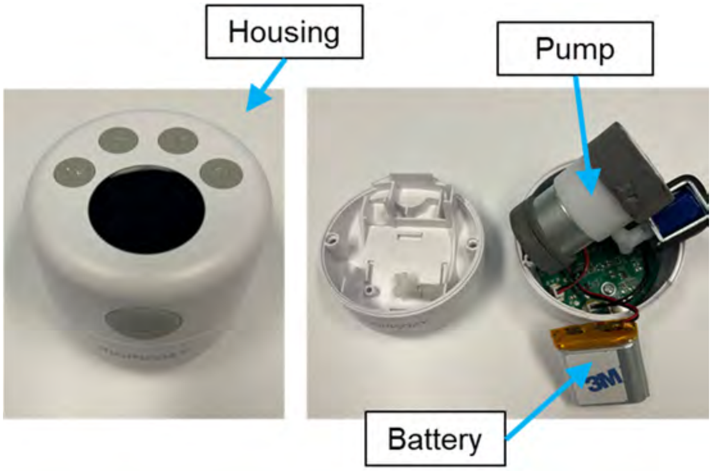
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S12**
29.2	a housing that includes: a rechargeable battery, a power charging circuit for controlling charging of the rechargeable battery, control electronics powered by the rechargeable battery, a pump powered by the rechargeable battery and configured to generate negative air pressure, and a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery;	The Momcozy S12 includes a housing that includes a rechargeable battery, a power charging circuit, control electronics, and a USB charging socket. The Momcozy S12 includes a housing, as shown below.  The Momcozy S12 housing includes a rechargeable battery. For example, the Momcozy S12 user guide also states "[t]his product has a built-in battery," and that they "recommend that you use a certified 5V==1A adapter to charge the Pump Motor." (Momcozy, S12 User Manual, p. 2.) The Momcozy website states that the Momcozy S12 is "[c]hargeable." (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) On information and belief, the Momcozy S12 housing includes a power charging circuit for controlling charging of the rechargeable battery and control electronics powered by the rechargeable battery because the Momcozy S12 is rechargeable and has buttons that change the operation of the pump. (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.	
Claim Language	**Momcozy S12**
	The Momcozy S12 housing includes a pump powered by the rechargeable battery and configured to generate negative air pressure. The Momcozy website advertises that "[t]his [S12] hands-free pump can be placed in the nursing bra so that you can pump milk anytime and anywhere. The wearable breastfeeding pump gives you the freedom to do multiple tasks during milk pumping." (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The website also states that the S12 breast pump has "9 Adjustable **Suction** Levels." (*Id.*) The Momcozy S12 housing includes a USB charging socket. As shown below, the Momcozy S12 includes a socket for receiving a USB cable.  (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

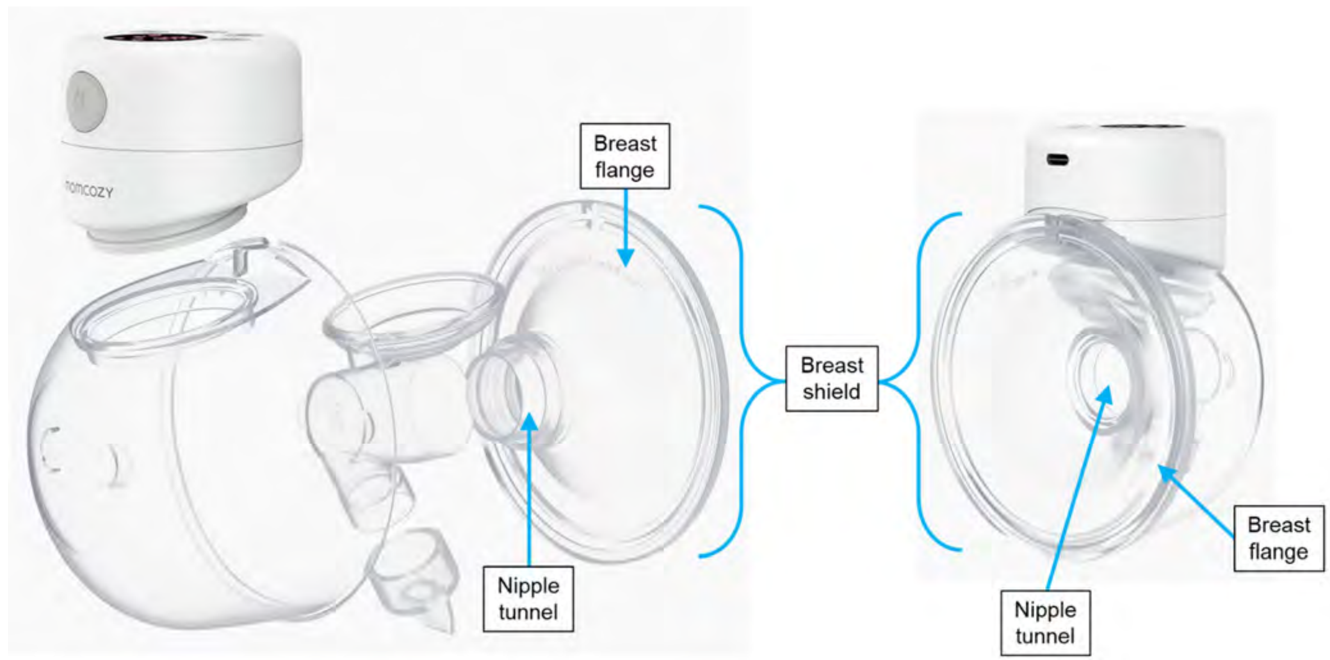
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S12**
29.3	a breast shield made up of a breast flange and a nipple tunnel;	The Momcozy S12 includes a breast shield made up of a breast flange and a nipple tunnel.  (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The Momcozy website indicates that the S12 product includes a "Flange Size: 24mm." (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S12**
29.4	a milk container that is configured to be attached to and removed from the housing; and	The Momcozy S12 includes a milk container that is configured to be attached to and removed from the housing. The Momcozy website clarifies that the S12 product includes a “milk collector (180ml/6oz).” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)  (https://www.youtube.com/watch?v=gQ0N_oNCJs0 at 0:24.)

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S12**
		 (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The Momcozy S12 user guide also illustrates removal and attachment of the housing to the milk container, as shown below. (Momcozy, S12 User Manual, p. 10.)

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

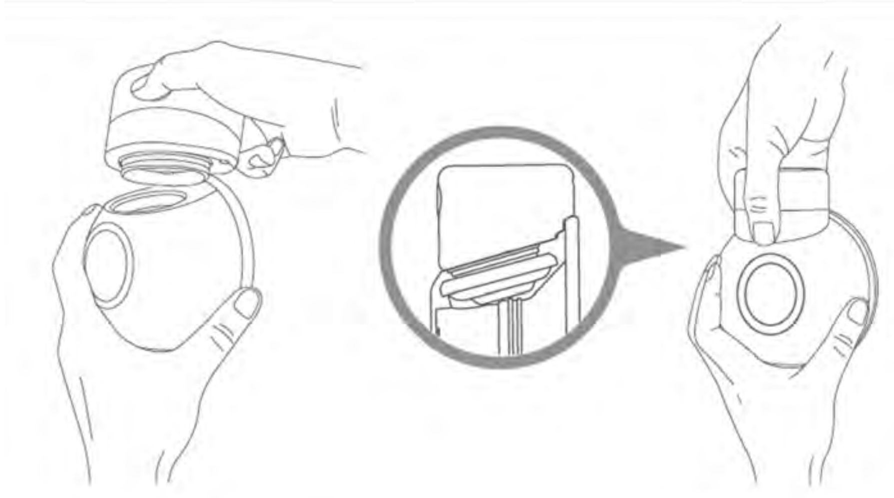
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S12**
		 (Picture 1) (Picture 2)

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S12**
29.5	a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing,	The Momcozy S12 includes a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing. As shown below, the Momcozy S12 includes a membrane.  (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The Momcozy website indicates that the S12 product includes a "silicone diaphragm." (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S12**
		 (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

Exhibit 19 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S12 Product

<table>
<tr><th colspan="3">The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12</th></tr>
<tr><td>29.6</td><td>the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.</td><td>The Momcozy S12 includes the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

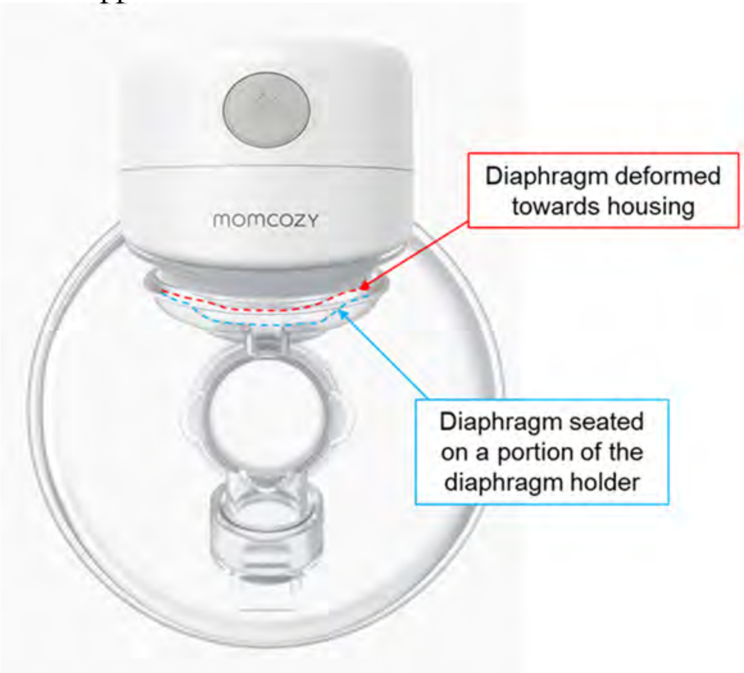
The Momcozy S12 product is advertised as having “9 Adjustable Suction Levels.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) On information and belief, when the pump is operated in the housing, it creates a change in air pressure that deforms the membrane to create negative pressure in the nipple tunnel.

</td></tr>
</table>

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Exhibit 20

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

<table>
<tr><th colspan="3">The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9 Pro</th></tr>
<tr><td colspan="3">Claim 29</td></tr>
<tr><td>29.P</td><td>A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:</td><td>The Momcozy S9 Pro is a breast pump device. The Momcozy S9 Pro is described as the “S9 Pro Wearable Breast Pump.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)

The Momcozy S9 Pro is a breast pump device that is configured as a self-contained device.


</td></tr>
</table>

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

<table>
<tr><th colspan="3">The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9 Pro</th></tr>
<tr><td></td><td></td><td>The Momcozy S9 Pro is an in-bra wearable device. The Momcozy website describes the Momcozy S9 Pro as that it “is designed to be worn with your standard nursing bra.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)


(https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)</td></tr>
</table>

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

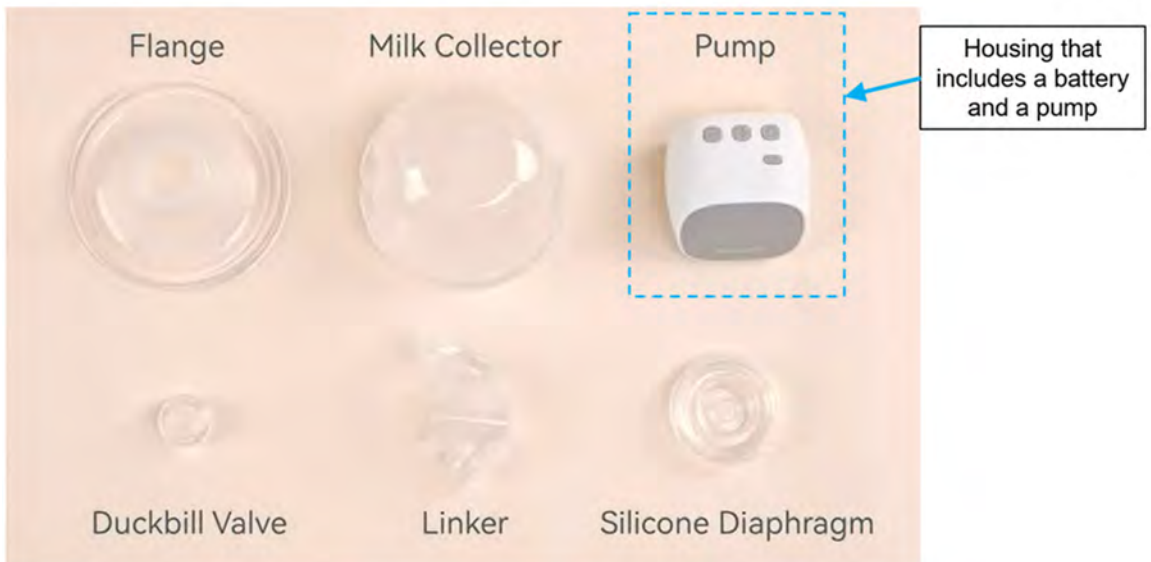
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S9 Pro**
29.1	a self-contained, in-bra wearable device comprising:	*See* 29.P.
29.2	a housing that includes: a rechargeable battery, a power charging circuit for controlling charging of the rechargeable battery, control electronics powered by the rechargeable battery, a pump powered by the rechargeable battery and configured to generate negative air pressure, and a Universal Serial Bus (USB) charging socket for transferring power to the power	The Momcozy S9 Pro includes a housing that includes a rechargeable battery, a power charging circuit, control electronics, a pump, and a USB charging socket.  Still image from Momcozy S9 Pro video (https://www.amazon.com/Momcozy-S9-Pro-Wearable-Hands-Free/dp/B0B74TFJCF?th=1.) The Momcozy S9 Pro housing includes a rechargeable battery. For example, the Momcozy S9 Pro user guide provides details on charging the battery. (Momcozy S9 Pro User Guide, p. 13.) The Momcozy

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9 Pro**
	charging circuit and the rechargeable battery;	website describes the Momcozy S9 Pro as “Long Battery Life.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.) On information and belief, the Momcozy S9 Pro housing includes a power charging circuit for controlling charging of the rechargeable battery and control electronics powered by the rechargeable battery because the Momcozy S9 Pro is rechargeable and has buttons that change the operation of the pump. The Momcozy S9 Pro housing includes a pump powered by the rechargeable battery and configured to generate negative air pressure. The Momcozy website advertises that the Momcozy S9 Pro includes a “Pump motor” and that the “S9 Pro hands-free pumps in a better efficiency with less time, saving more time for moms.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump?variant=42680176738502.) The Momcozy website describes the Momcozy S9 Pro as having “Hospital grade 280 ~ 300mmHg suction range.” (*Id.*) The Momcozy S9 Pro pump generates negative air pressure. For example, the Momcozy website states that the Momcozy S9 Pro breast pump has “S9 Pro breast pump owns 2 modes of expression and mixed suction with 9 intensity levels for each.” (*Id.*) The Momcozy S9 Pro user guide also states that the “Momcozy pump has 9 vacuum pressure settings for each mode, giving you control over what feels comfortable and works most efficiently in both stimulation and expression modes.” (Momcozy S9 Pro User Guide, p. 12.) The Momcozy S9 Pro housing includes a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery. For example, the Momcozy S9 Pro is “[e]quipped with a bigger capacity battery and fast charging Type-C charging port.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9 Pro**
		

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

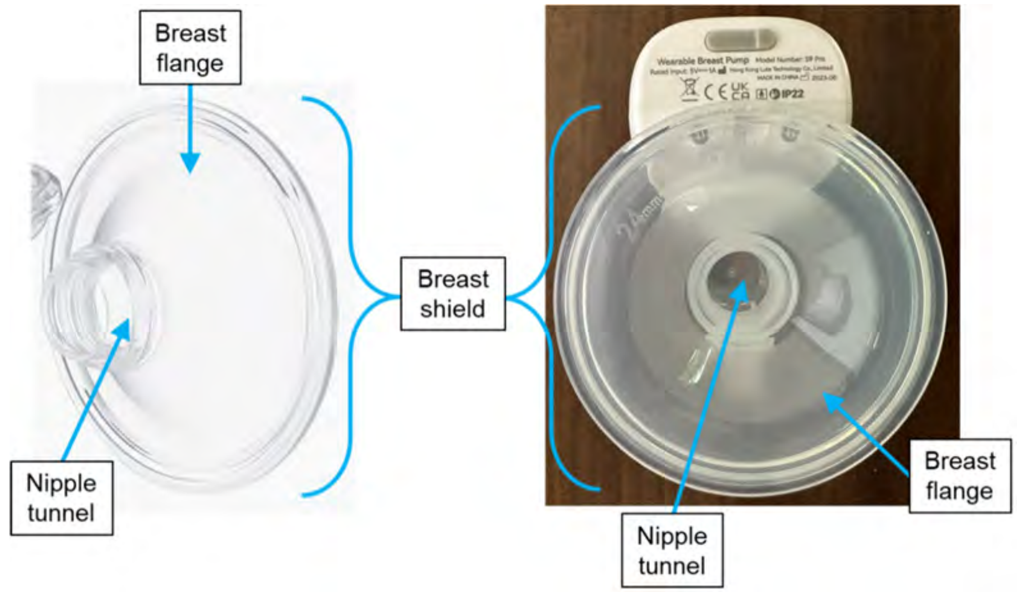
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S9 Pro**
29.3	a breast shield made up of a breast flange and a nipple tunnel;	The Momcozy S9 Pro includes a breast shield made up of a breast flange and a nipple tunnel.  The Momcozy website states that the Momcozy S9 Pro includes a "Default Flange Size: 24mm." (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.) As shown above, the breast shield includes a breast flange and a nipple tunnel.
29.4	a milk container that is configured to be attached to and removed from the housing; and	The Momcozy S9 Pro includes a milk container. The Momcozy website states that the Momcozy S9 Pro includes a "Milk Collector (180ml)." (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9 Pro**
		

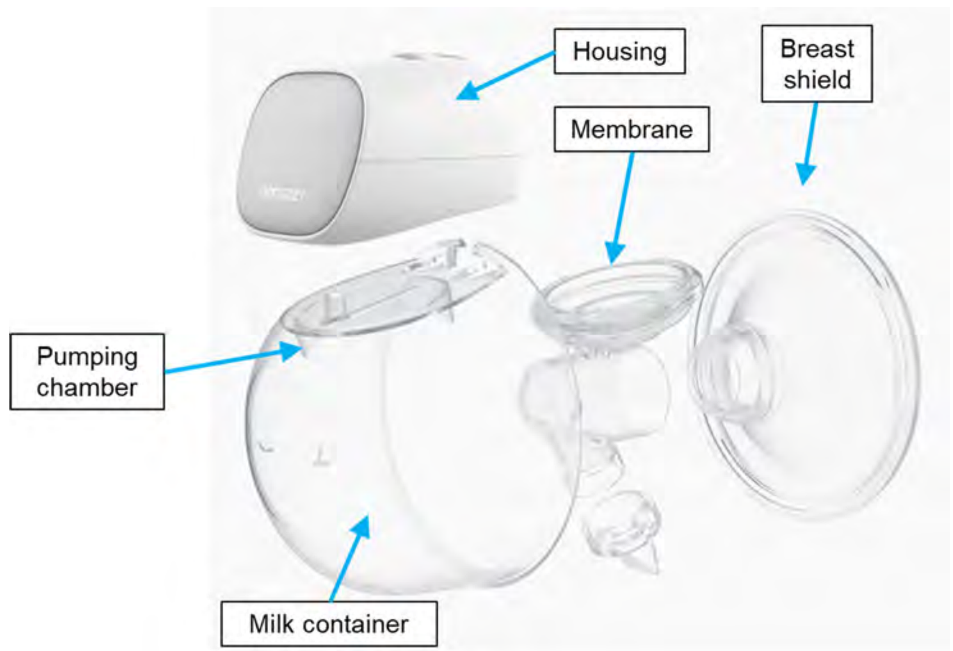
Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9 Pro**
		The Momcozy S9 Pro milk container is configured to be attached to and removed from the housing. 

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

<table>
<tr><th colspan="3">The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9 Pro</th></tr>
<tr><td>29.5</td><td>a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing,</td><td>The Momcozy S9 Pro includes a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing.

As shown below, the Momcozy S9 Pro includes a membrane.



(https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)

The Momcozy website clarifies that the Momcozy S9 Pro product includes a “Silicone Diaphragm.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)</td></tr>
</table>

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9 Pro**
		As shown below, the membrane is seated on a diaphragm holder that is fixed to an external surface of the housing to define a pumping chamber. 

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

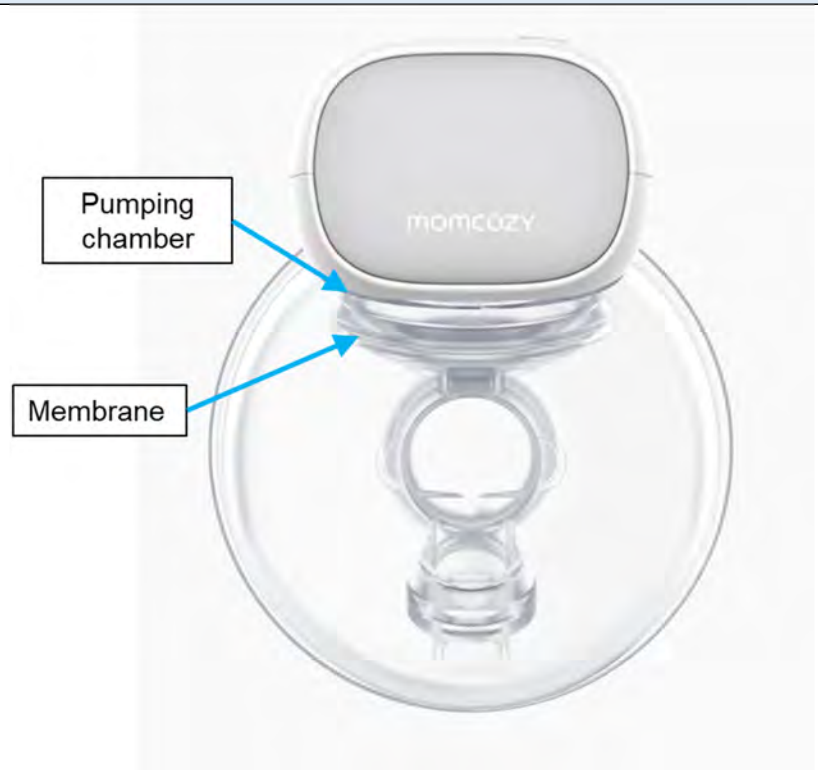
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9 Pro**
		

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

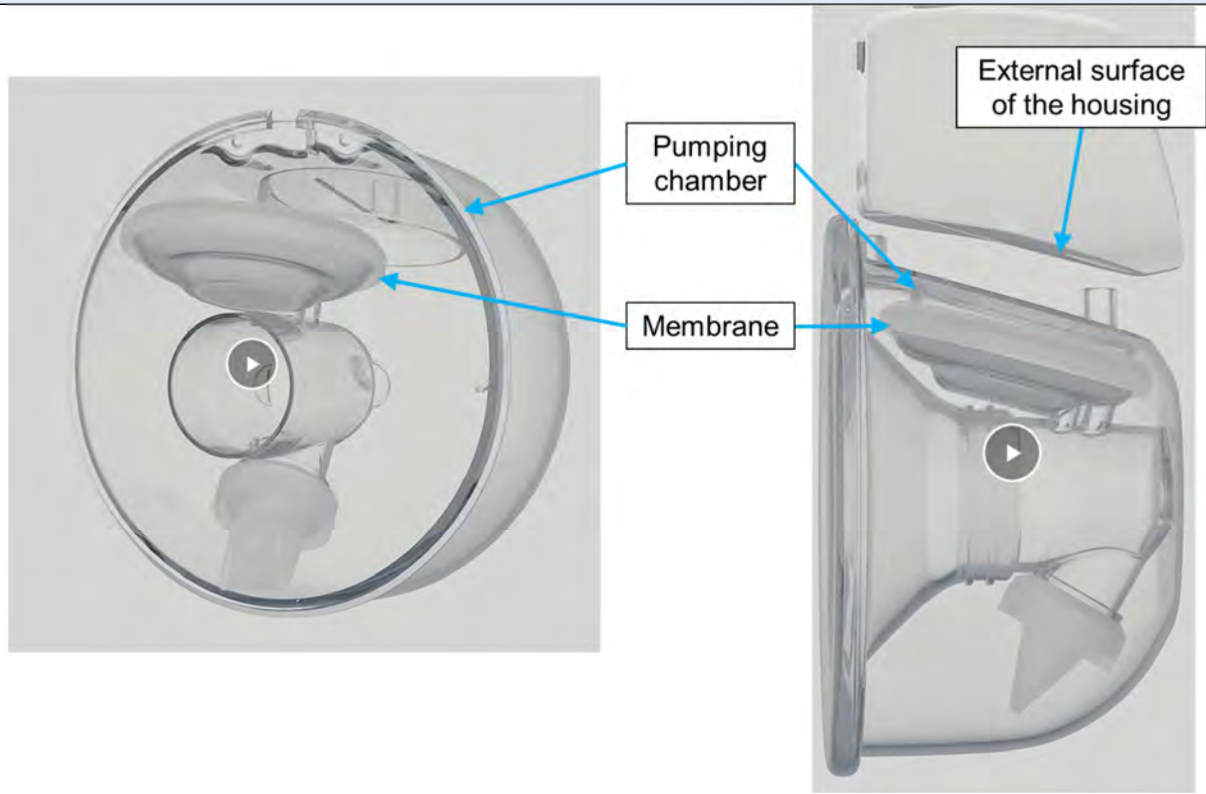
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S9 Pro**
		

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

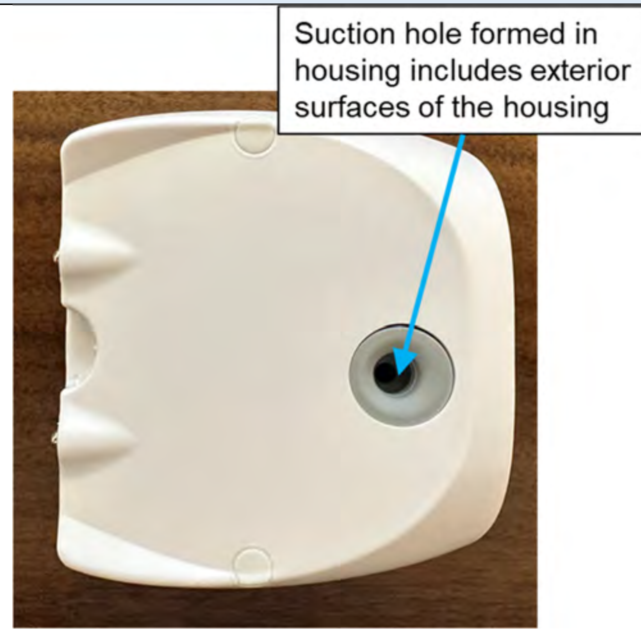
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
	Claim Language	**Momcozy S9 Pro**
		

Exhibit 20 – U.S. Patent No. 11,413,380 – Infringement Claim Chart for Momcozy S9 Pro Product

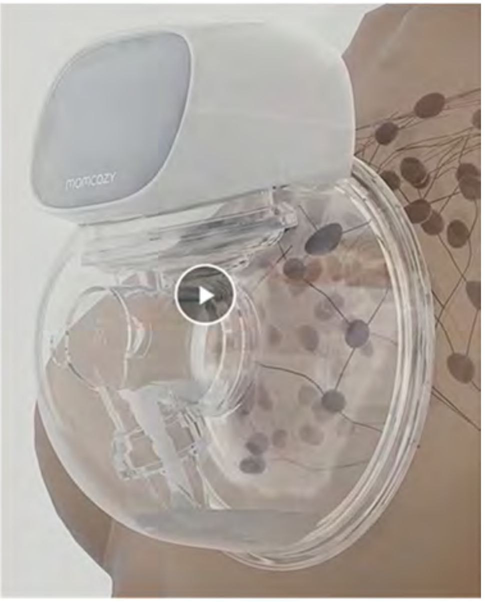
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9 Pro**
29.6	the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.	The Momcozy S9 Pro includes the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. The Momcozy S9 Pro user guide states that the “Momcozy pump has 9 vacuum pressure settings for each mode.” (Momcozy S9 Pro User Guide, p. 12.) As shown in the images below, the membrane deforms to create negative air pressure in the nipple tunnel.   (https://www.amazon.com/vdp/000d21f3cc6741eba9f74d3896d39d92?product=B0BXH2PM3Z&ref=cm_sw_em_r_ib_dt_0F7jkWeZZk35u.)

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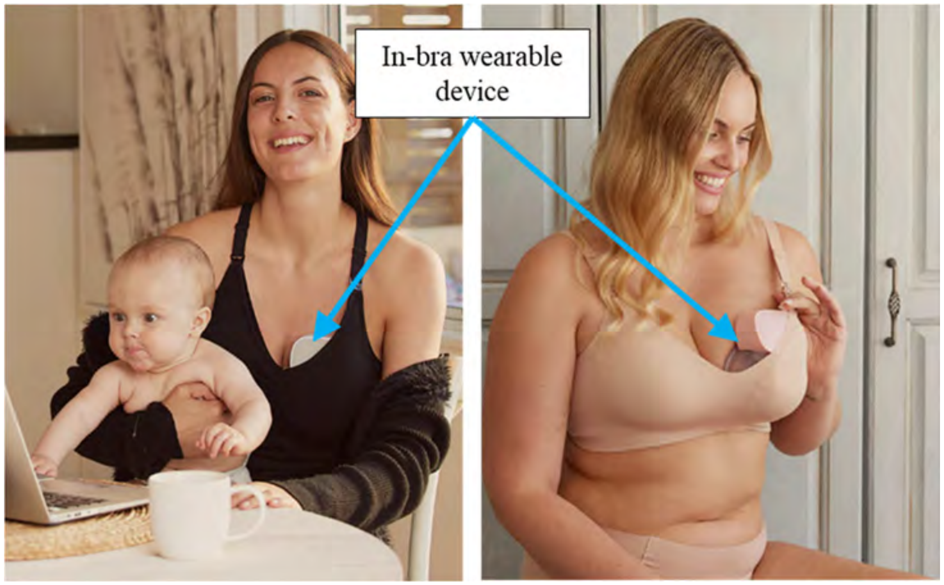
Exhibit 21

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9**
Claim 29		
29.P	A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:	The Momcozy S9 is a breast pump device. The Momcozy S9 is described as a “2 Mode Wearable Electric Breast Pump.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) The Momcozy S9 is a breast pump device that is configured as a self-contained device, as shown below. 

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

<table>
<tr><th colspan="3">The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9</th></tr>
<tr><td></td><td></td><td>The Momcozy S9 is an in-bra wearable device.


(https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)

As shown above, the Momcozy S9 is in-bra wearable. The Momcozy website explains that the Momcozy S9 is described as “Wearable, Fit Inside Bras.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) The Momcozy S9 “pump is able to fit inside normal nursing bras for the whole day to get rid of ‘finding nursing room’ and ‘repeated bra-offs’ games.” (Id.)</td></tr>
<tr><td>29.1</td><td>a self-contained, in-bra wearable device comprising:</td><td>See 29.P.</td></tr>
</table>

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

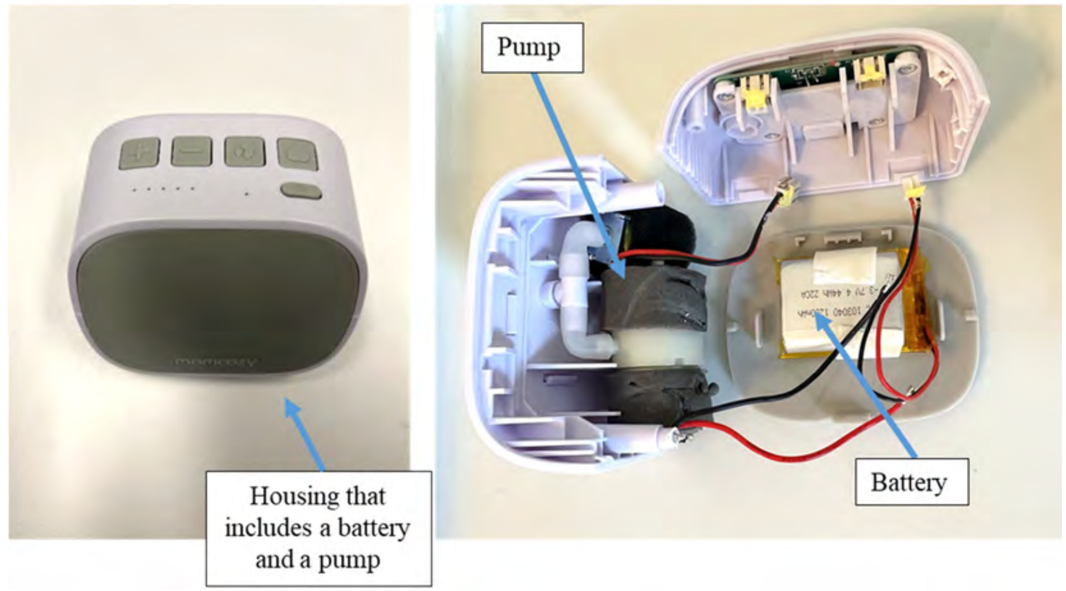
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9**
29.2	a housing that includes: a rechargeable battery, a power charging circuit for controlling charging of the rechargeable battery, control electronics powered by the rechargeable battery, a pump powered by the rechargeable battery and configured to generate negative air pressure, and a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery;	The Momcozy S9 includes a housing that includes a rechargeable battery, a power charging circuit, control electronics, a pump, and a USB charging socket.  The Momcozy S9 housing includes a rechargeable battery. For example, the Momcozy S9 user guide states “[t]his product has a built-in battery,” and that they “recommend that you use a certified 5V==1A adapter to charge the battery.” (Momcozy, S9 User Manual, p. 2.) On information and belief, the Momcozy S9 housing includes a power charging circuit for controlling charging of the rechargeable battery and control electronics powered by the rechargeable battery because the Momcozy S9 is rechargeable and it has buttons that change the operation of the pump. The Momcozy S9 housing includes a pump powered by the battery and generating negative air pressure. For example, the Momcozy website advertises that the “wearable hands-free pump can be worn inside a

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9**
		standard nursing bra, so you can pump completely hands-free anytime, anywhere.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) The Momcozy S9 user guide also identifies the housing as the “pump motor,” as shown as item 4 in the figure below. (Momcozy, S9 User Manual, p. 1.) The Momcozy S9 housing includes a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery. The Momcozy website explains “[o]ne charge for 3-4 using times.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) Further, the Momcozy website explains that the Momcozy S9 includes “1 USB Cable.” (*Id.*)

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.	
Claim Language	**Momcozy S9**
	 The Momcozy S9 pump generates negative air pressure. For example, the Momcozy website states that the S9 breast pump has “5 Adjustable ***Suction*** Levels.” (*Id.*, under “Feature” tab (emphasis added).)

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

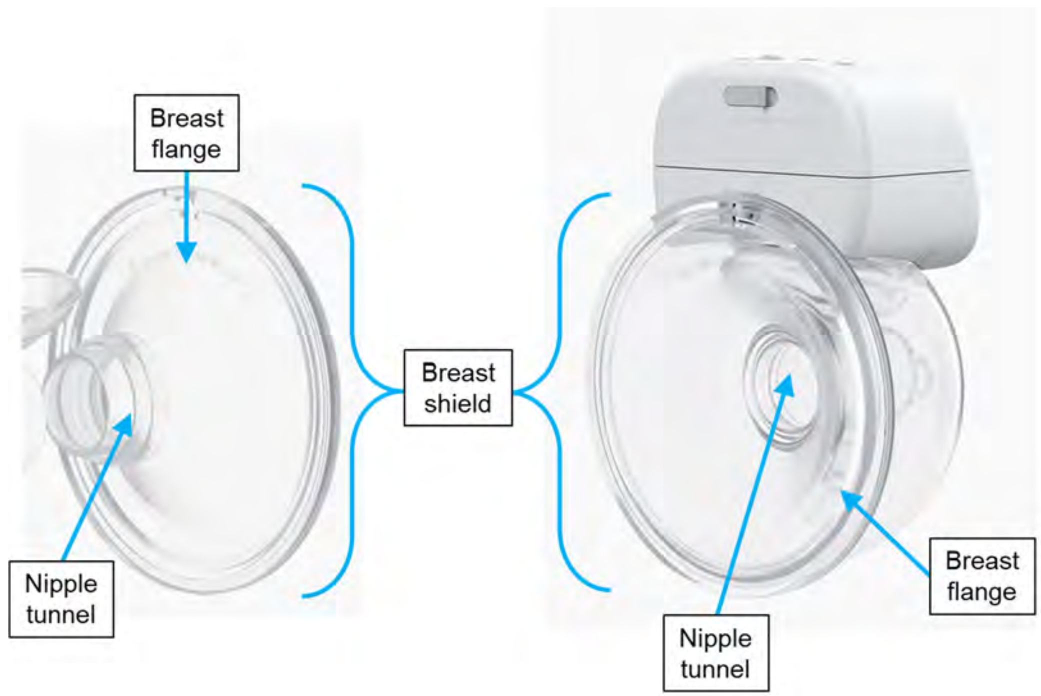
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S9**
29.3	a breast shield made up of a breast flange and a nipple tunnel;	The Momcozy S9 includes a breast shield that includes a breast flange and a nipple tunnel. For example, the Momcozy S9 includes a "Silicone Shield (24 mm)." (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)  (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

<table>
<tr><th colspan="3">The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>Nipple measurement</th><th>Flange</th></tr>
<tr><td>11-13mm</td><td>17mm</td></tr>
<tr><td>14-16mm</td><td>19mm</td></tr>
<tr><td>17-19mm</td><td>21mm</td></tr>
<tr><td>20-22mm</td><td>24mm</td></tr>
<tr><td>23-25mm</td><td>27mm</td></tr>
</table>
</td></tr>
</table>

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

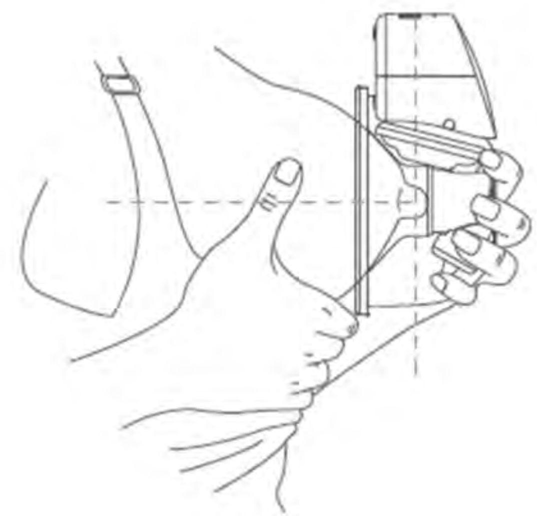
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S9**
		 Momcozy, S9 User Manual, p. 1.  Momcozy, S9 User Manual, p. 6.

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

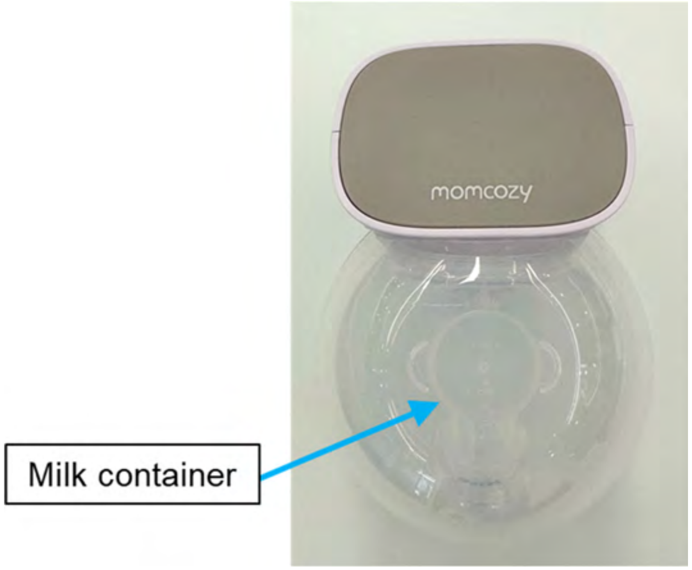
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9**
29.4	a milk container that is configured to be attached to and removed from the housing; and	The Momcozy S9 includes a milk container.  The Momcozy website shows that the S9 product includes a “milk collector (180ml/6oz).” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.		
Claim Language		**Momcozy S9**
		The Momcozy S9 milk container is configured to be attached to and removed from the housing.  The S9 user guide illustrates removal and attachment of the housing to the milk container, as shown below. (Momcozy, S9 User Manual, p. 10.)

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

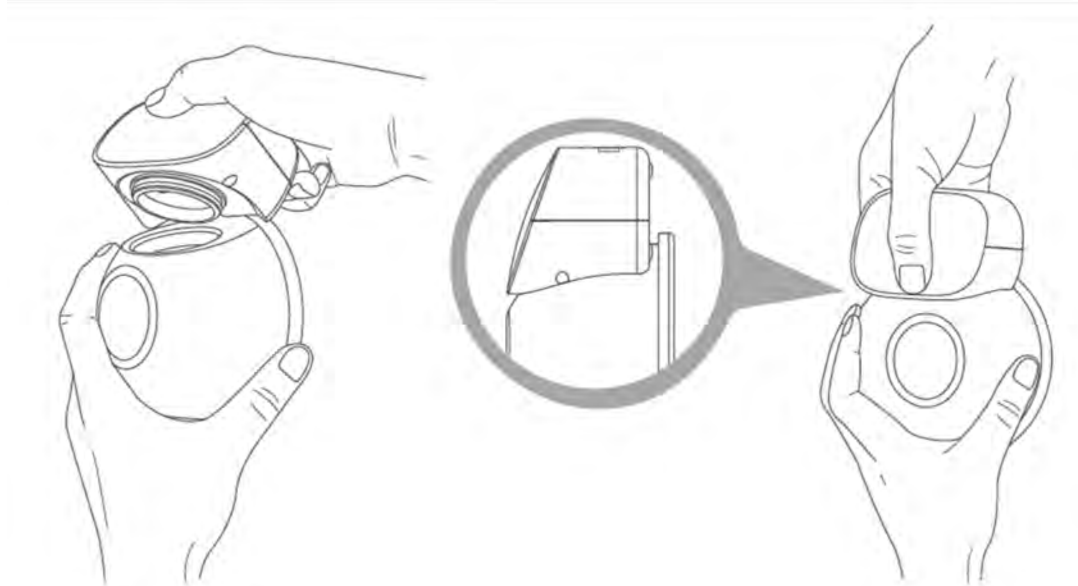
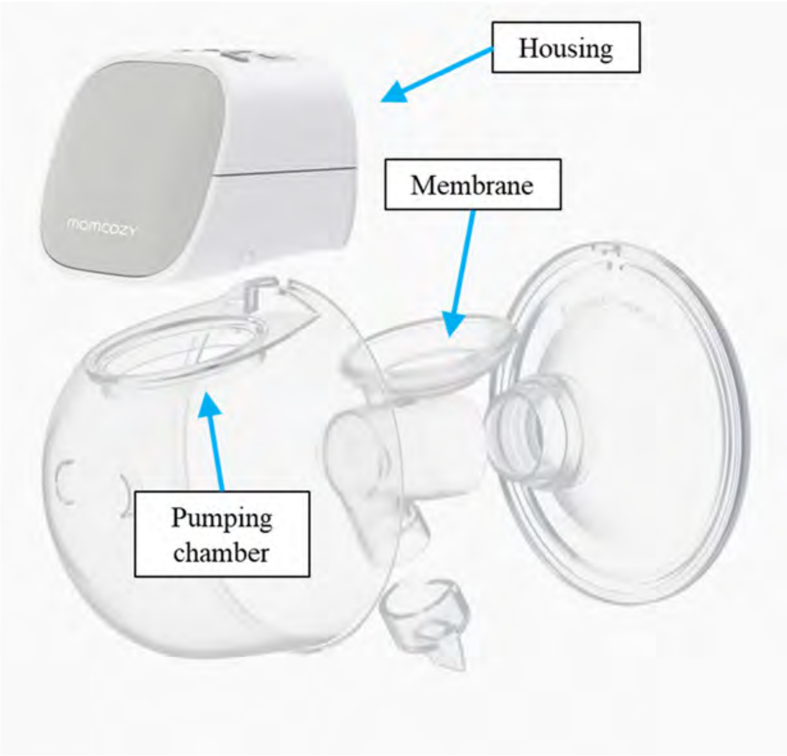
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
Claim Language		**Momcozy S9**
		 (picture 1) (picture 2)

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

<table>
<tr><th colspan="3">The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9</th></tr>
<tr><td>29.5</td><td>a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing,</td><td>The Momcozy S9 includes a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing.

As shown below, the Momcozy S9 includes a membrane.



(https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)</td></tr>
</table>

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the '380 Patent.		
	Claim Language	**Momcozy S9**
		As shown below, the membrane defines a pumping chamber at least in part with an external surface of the housing.  (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)

Exhibit 21 – U.S. Patent No. 11,357,380 – Infringement Claim Chart for Momcozy S9 Product

<table>
<tr><th colspan="3">The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 29 of the ’380 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9</th></tr>
<tr><td>29.6</td><td>the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.</td><td>The Momcozy S9 includes the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

The Momcozy S9 product is advertised as having “5 Adjustable Suction Levels and 2 Modes.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) On information and belief, when the pump is operated in the housing, it creates a change in air pressure that deforms the membrane to create negative pressure in the nipple tunnel.

</td></tr>
</table>

20671677

Exhibit 22

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

1 result found for **Owner Operator Number :**
10083690

New Search[6]

Establishment Name	▲[7] ▼[8]	Registration Number	Current Registration Yr
SHENZHEN LUTEJIACHENG TECHNOLOGY CO., LTD.[9]	CHINA	3021376102	2023

- Pump, Breast, Powered - Momcozy Wearable Breast Pump (Model S10); Momcozy Wearable Breast Pump (Model X1); [10] — Foreign Exporter; Manufacturer
- Pump, Breast, Powered - Momcozy Wearable Breast Pump(M5); [11] — Foreign Exporter; Manufacturer
- Pump, Breast, Powered - Momcozy Wearable Breast Pump (S9 Pro & S12 Pro); [12] — Manufacturer

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6. ../cfrl/rl.cfm
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13. ./rl.cfm

Page Last Updated: 08/14/2023

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Exhibit 23

US011357893B2

(12) **United States Patent**
O'Toole et al.

(10) **Patent No.: US 11,357,893 B2**
(45) **Date of Patent: Jun. 14, 2022**

(54) **BREAST PUMP SYSTEM**

(71) Applicant: **CHIARO TECHNOLOGY LIMITED**, London (GB)

(72) Inventors: **Jonathan O'Toole**, London (GB); **Adam Rollo**, London (GB); **Andrew Carr**, London (GB)

(73) Assignee: **Chiaro Technology Limited**, London (GB)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **17/203,050**

(22) Filed: **Mar. 16, 2021**

(65) **Prior Publication Data**

US 2021/0196873 A1 Jul. 1, 2021

Related U.S. Application Data

(63) Continuation of application No. 17/181,057, filed on Feb. 22, 2021, which is a continuation of application (Continued)

(30) **Foreign Application Priority Data**

Jun. 15, 2017 (GB) 1709561
Jun. 15, 2017 (GB) 1709564
(Continued)

(51) **Int. Cl.**
A61M 1/06 (2006.01)
G16H 40/63 (2018.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 1/062*** (2014.02); ***A61M 1/06*** (2013.01); ***A61M 1/066*** (2014.02); ***G16H 40/63*** (2018.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 1/06; A61M 1/062; A61M 1/066; A61J 13/00; A41C 4/04
See application file for complete search history.

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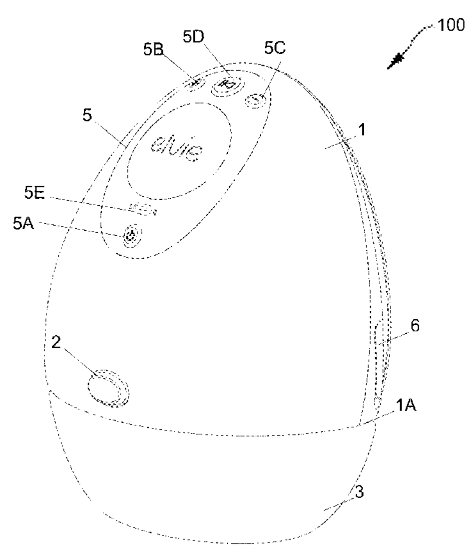
(Continued)

Primary Examiner — Nathan R Price
Assistant Examiner — Courtney B Fredrickson
(74) *Attorney, Agent, or Firm* — Sterne, Kessler, Goldstein & Fox P.L.L.C.

(57) **ABSTRACT**

The invention is a wearable breast pump system including a housing shaped at least in part to fit inside a bra and a piezo air-pump. The piezo air-pump is fitted in the housing and forms part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure. The diaphragm is removably mounted on a breast shield.

28 Claims, 44 Drawing Sheets



Related U.S. Application Data

No. 16/009,547, filed on Jun. 15, 2018, now Pat. No. 10,926,011.

(30) **Foreign Application Priority Data**

Jun. 15, 2017 (GB) 1709566
Jun. 1, 2018 (GB) 1809036

(51) **Int. Cl.**
A41C 3/04 (2006.01)
A61J 9/00 (2006.01)
A61M 39/22 (2006.01)
A61M 39/24 (2006.01)

(52) **U.S. Cl.**
CPC . *A41C 3/04* (2013.01); *A61J 9/00* (2013.01); *A61M 39/223* (2013.01); *A61M 39/24* (2013.01); *A61M 2205/07* (2013.01); *A61M 2205/10* (2013.01); *A61M 2205/3313* (2013.01); *A61M 2205/3327* (2013.01); *A61M 2205/3334* (2013.01); *A61M 2205/3344* (2013.01); *A61M 2205/3389* (2013.01); *A61M 2205/3553* (2013.01); *A61M 2205/3584* (2013.01); *A61M 2205/3606* (2013.01); *A61M 2205/502* (2013.01); *A61M 2205/505* (2013.01); *A61M 2205/52* (2013.01); *A61M 2205/581* (2013.01); *A61M 2205/582* (2013.01); *A61M 2205/583* (2013.01); *A61M 2205/584* (2013.01); *A61M 2205/587* (2013.01); *A61M 2205/6054* (2013.01); *A61M 2205/702* (2013.01); *A61M 2205/7536* (2013.01); *A61M 2205/80* (2013.01); *A61M 2205/8206* (2013.01); *A61M 2209/082* (2013.01); *A61M 2209/088* (2013.01)

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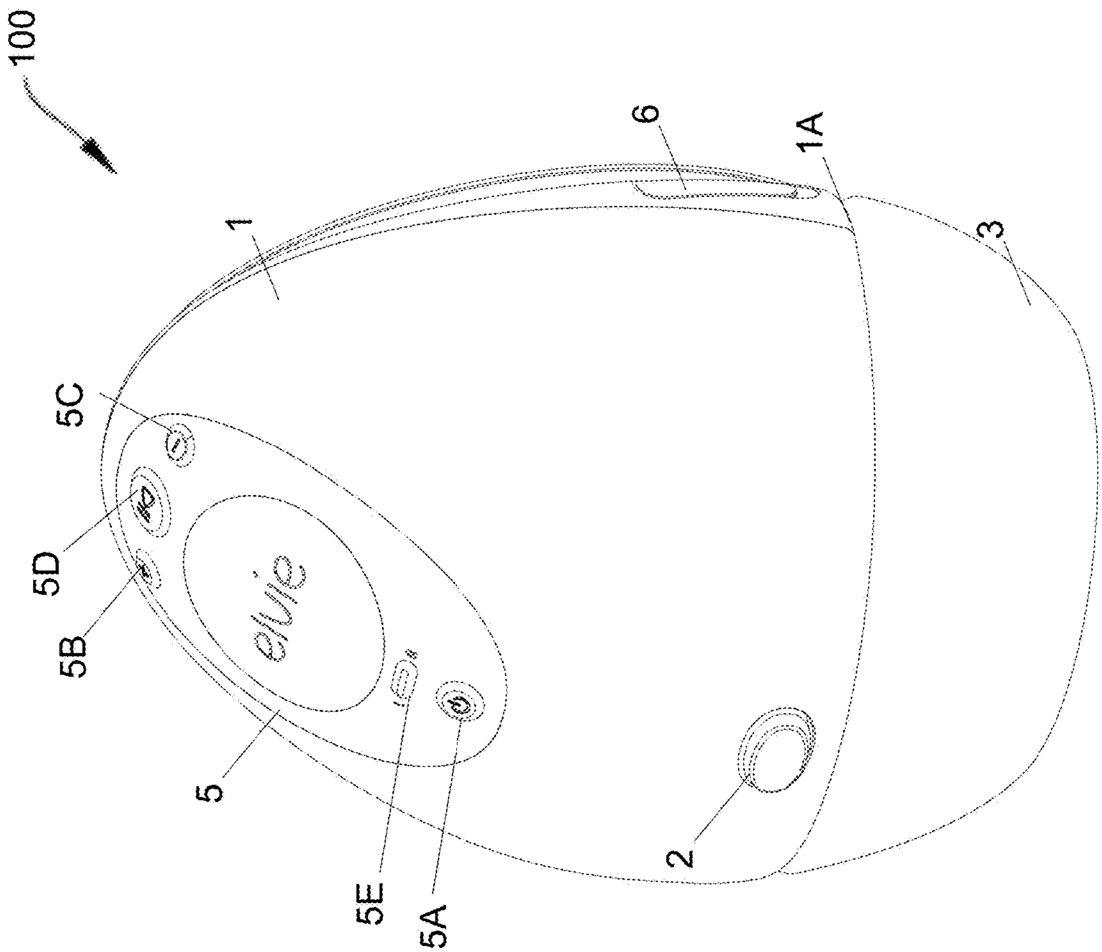

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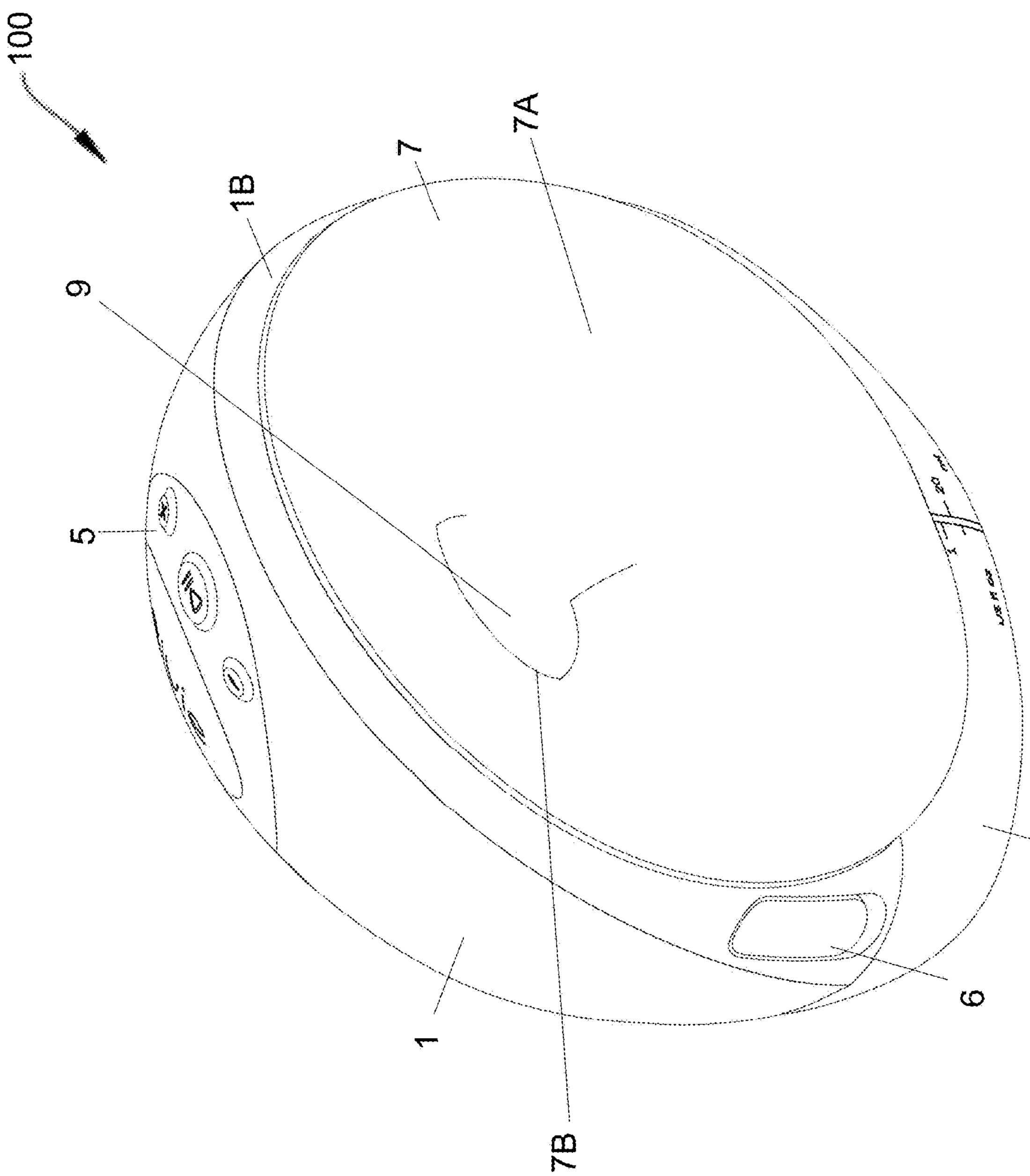
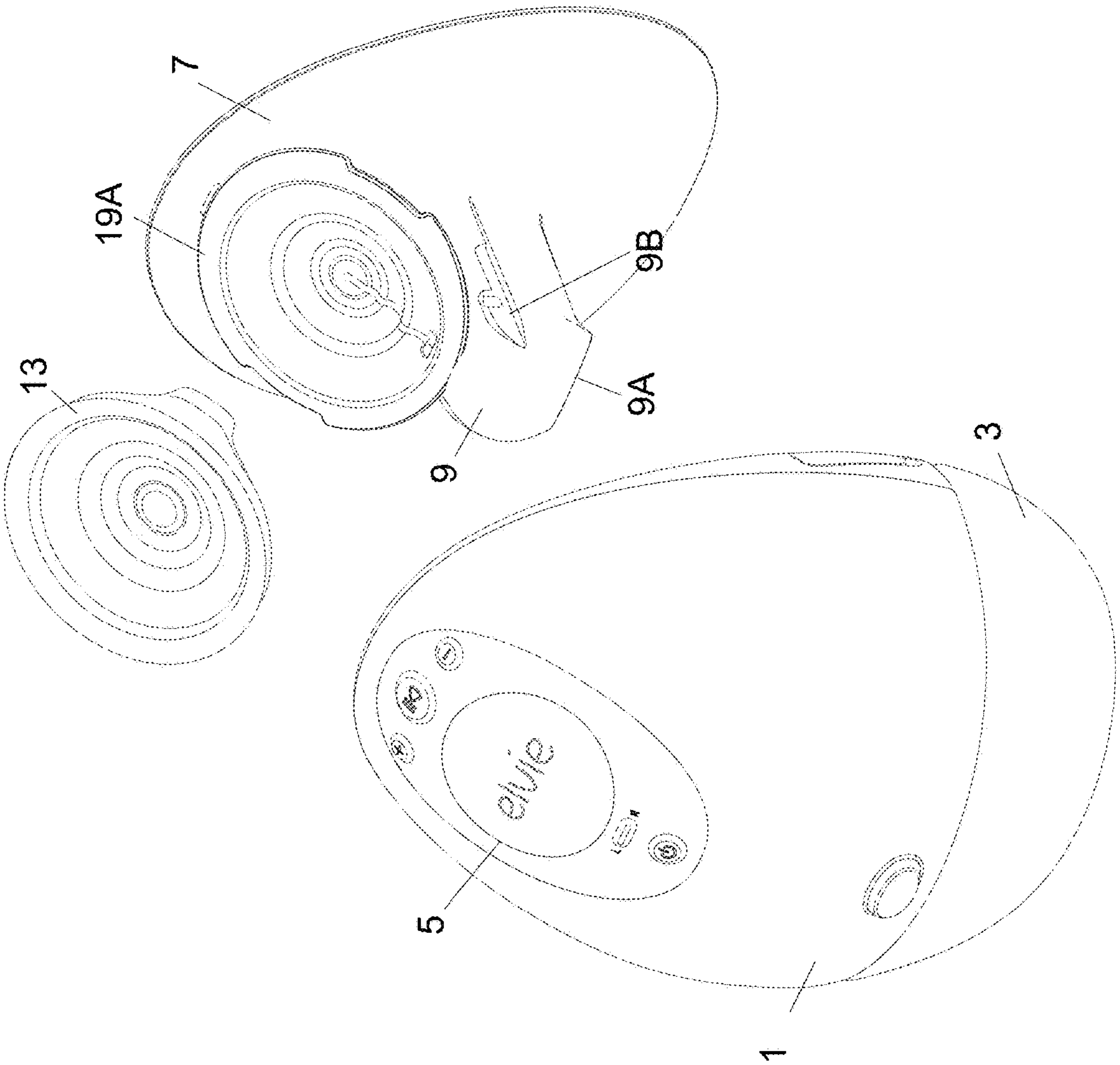


FIGURE 2



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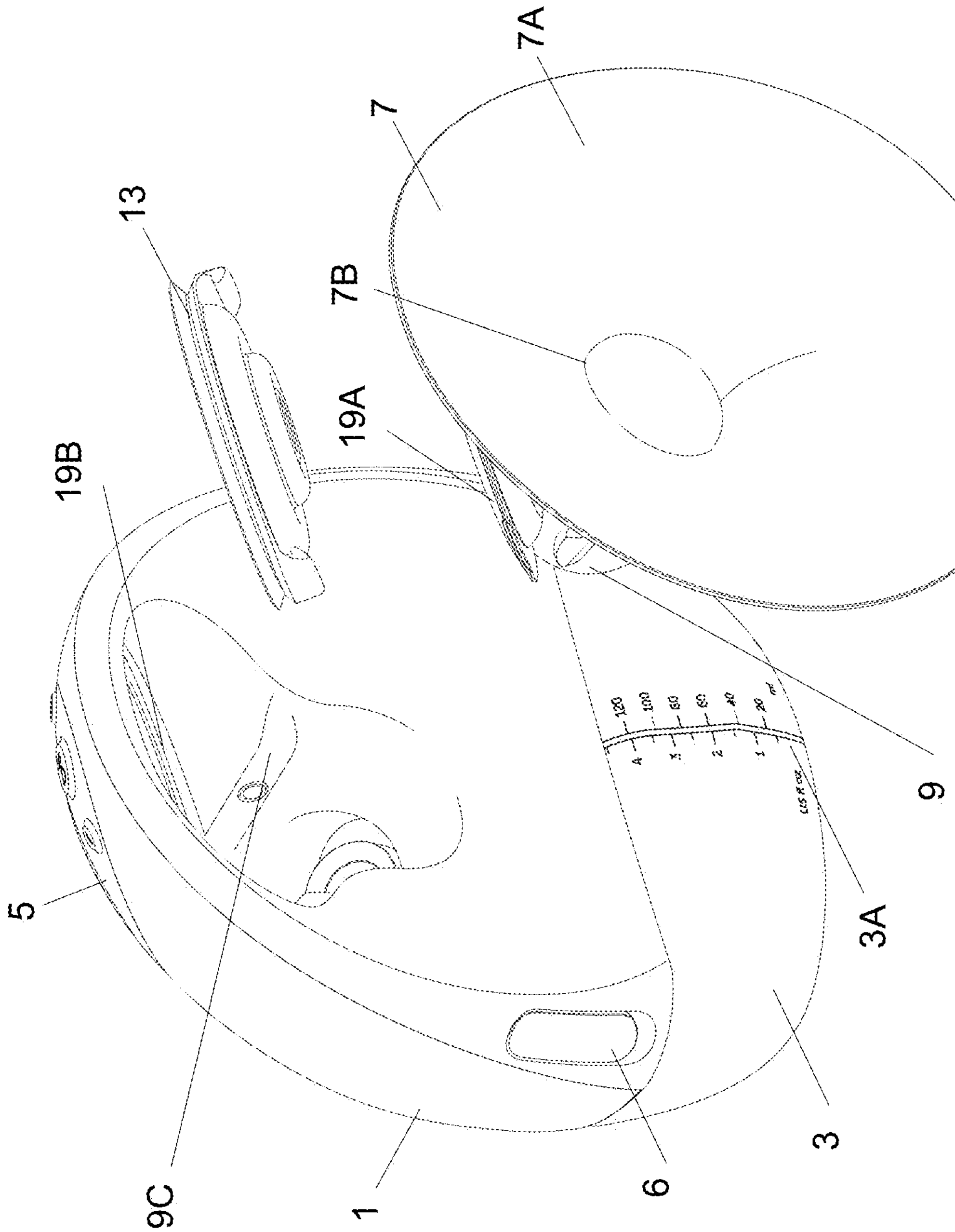

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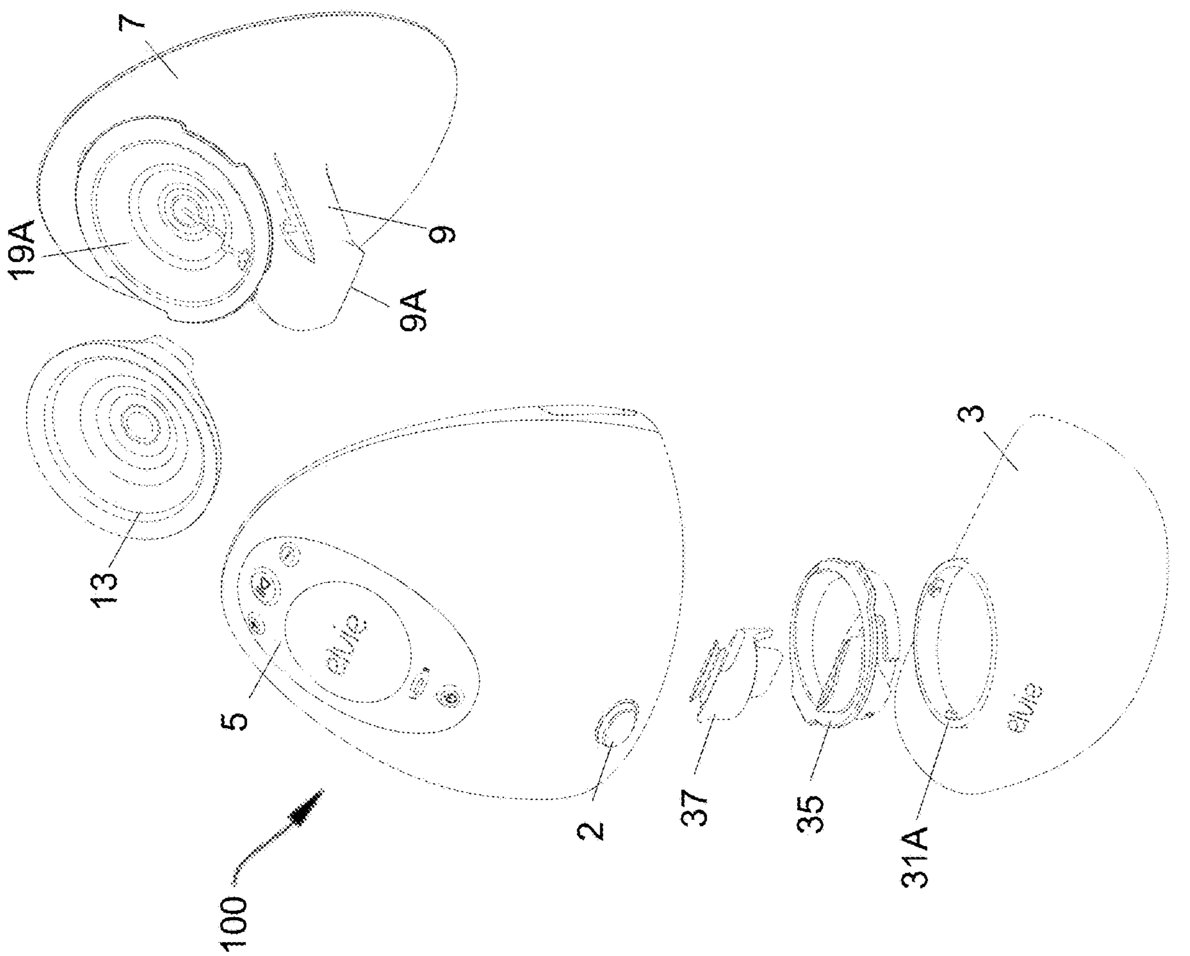

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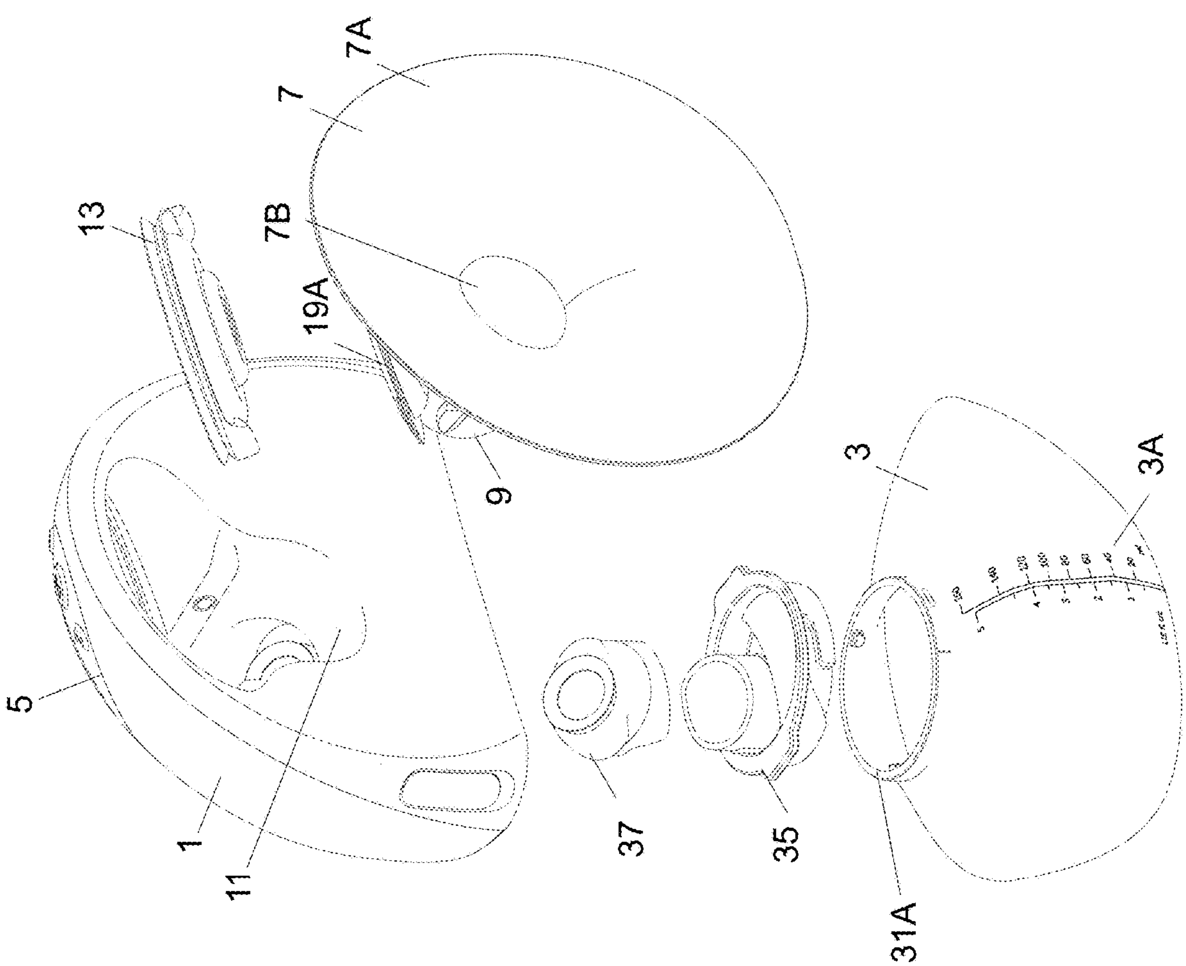

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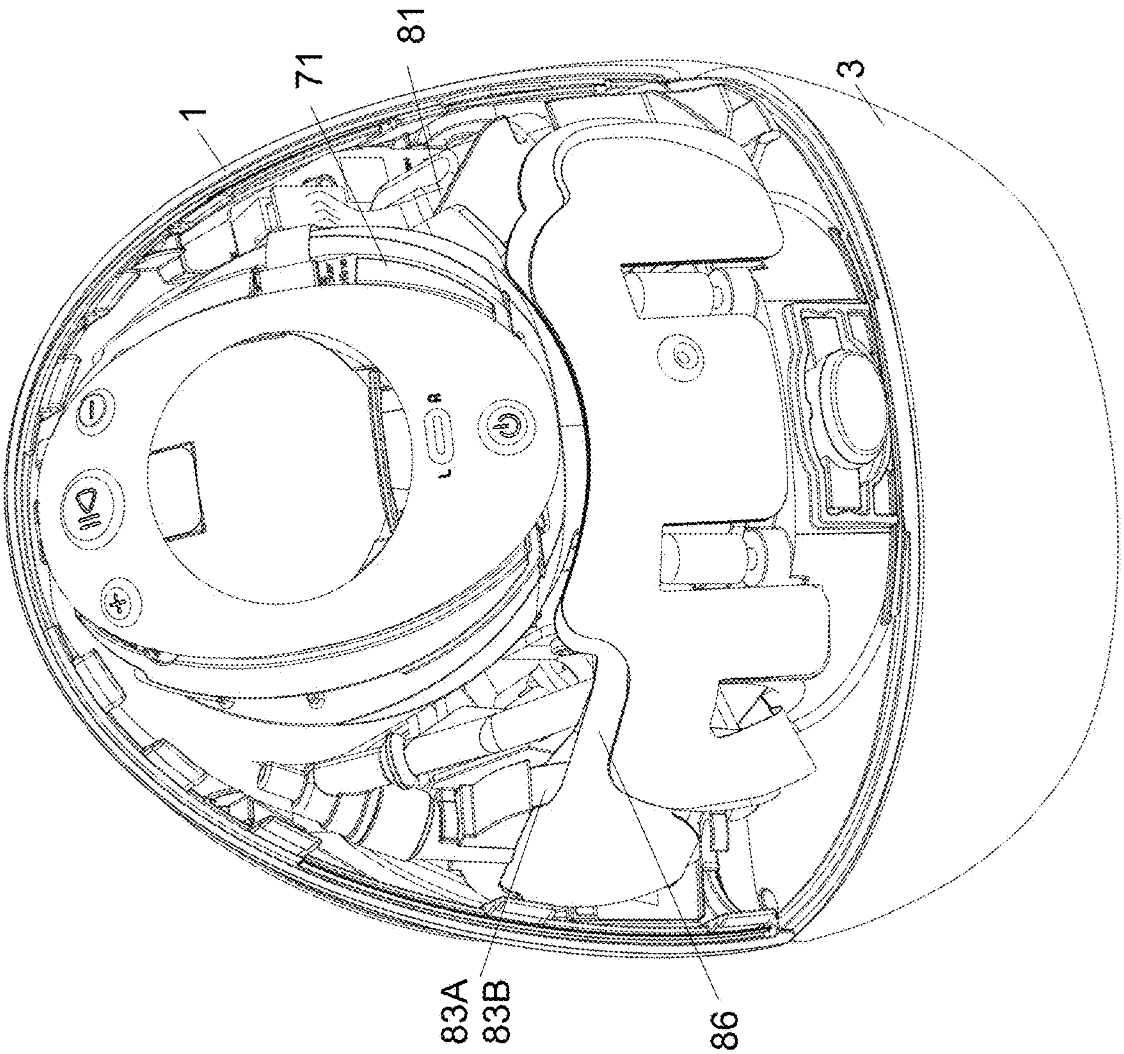

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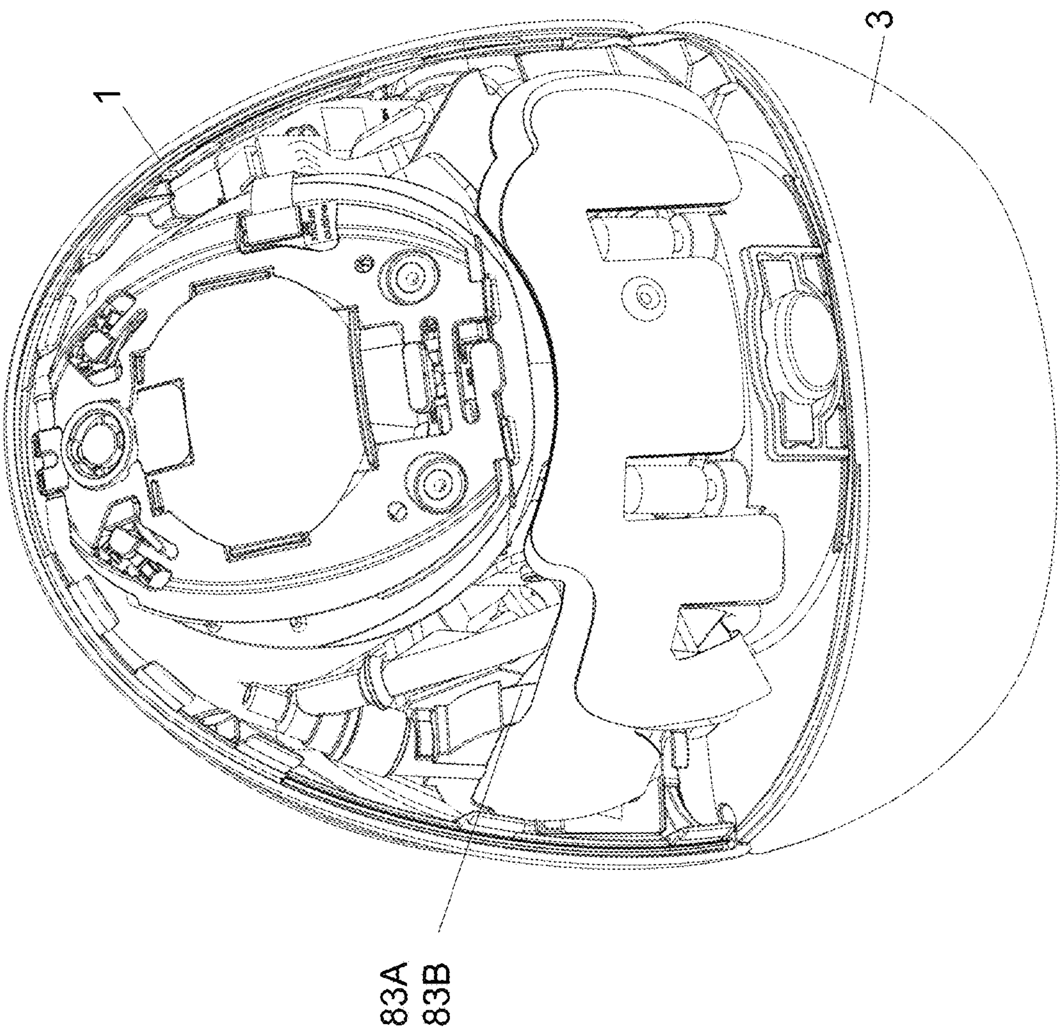

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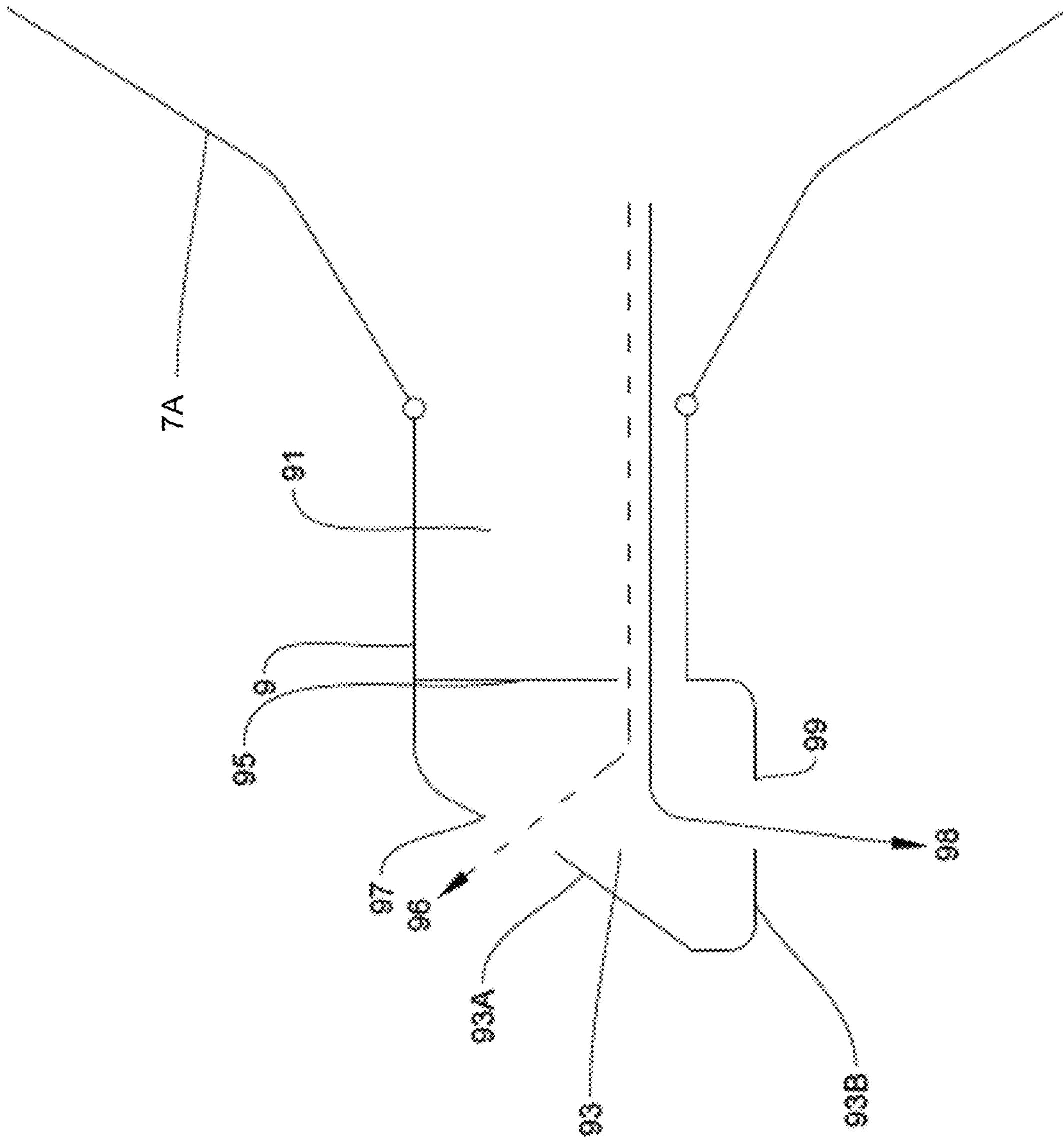

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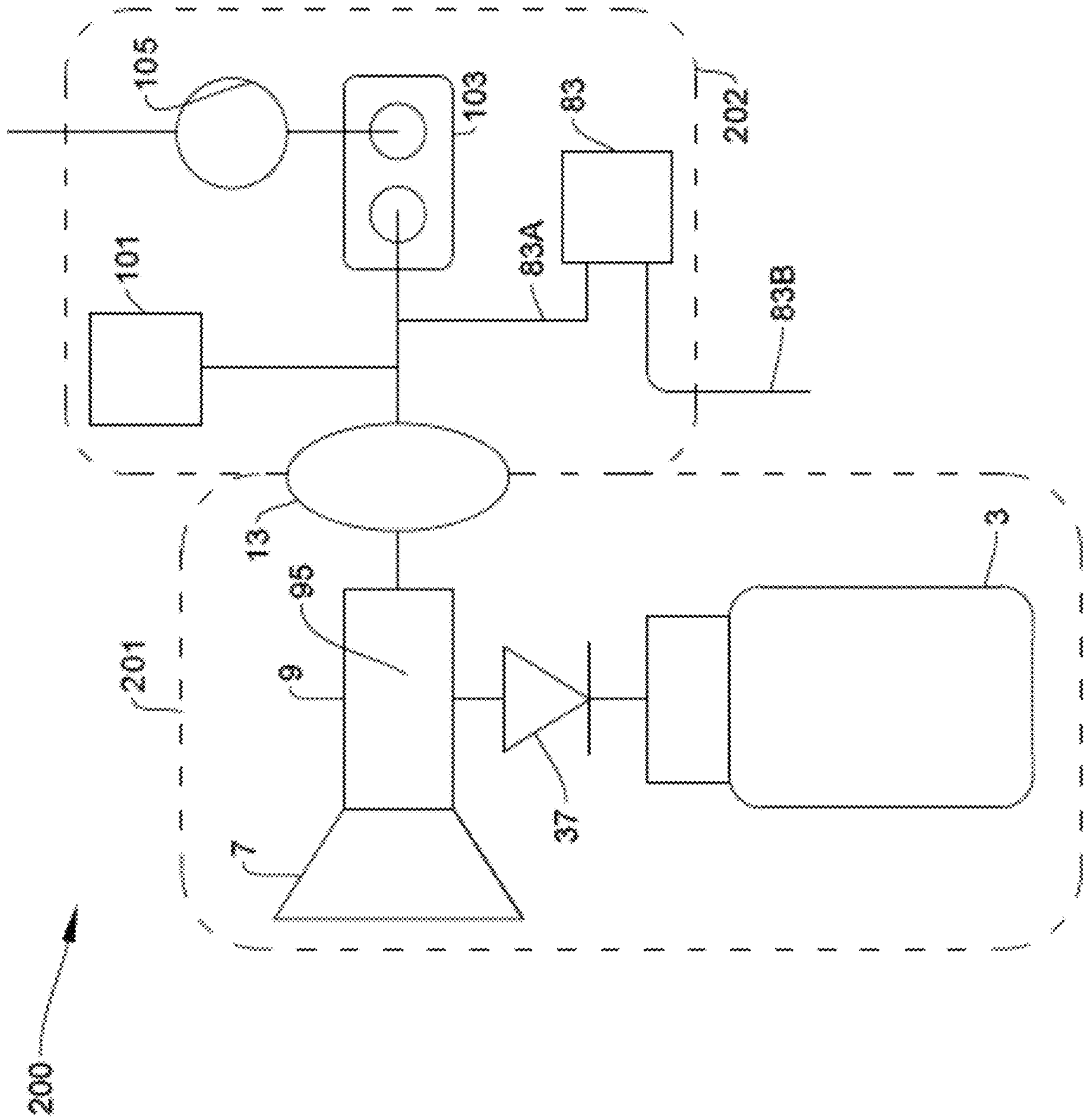

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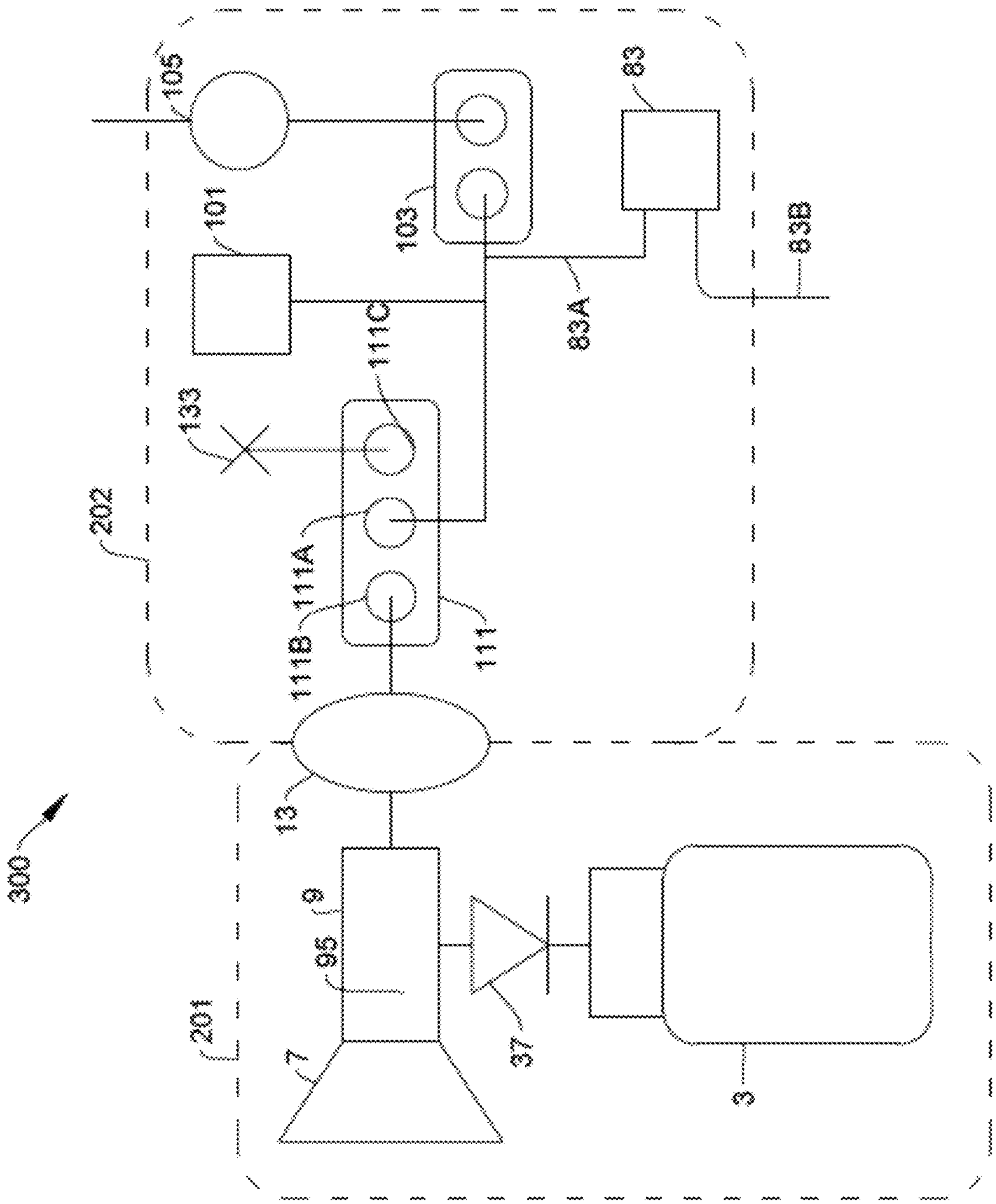
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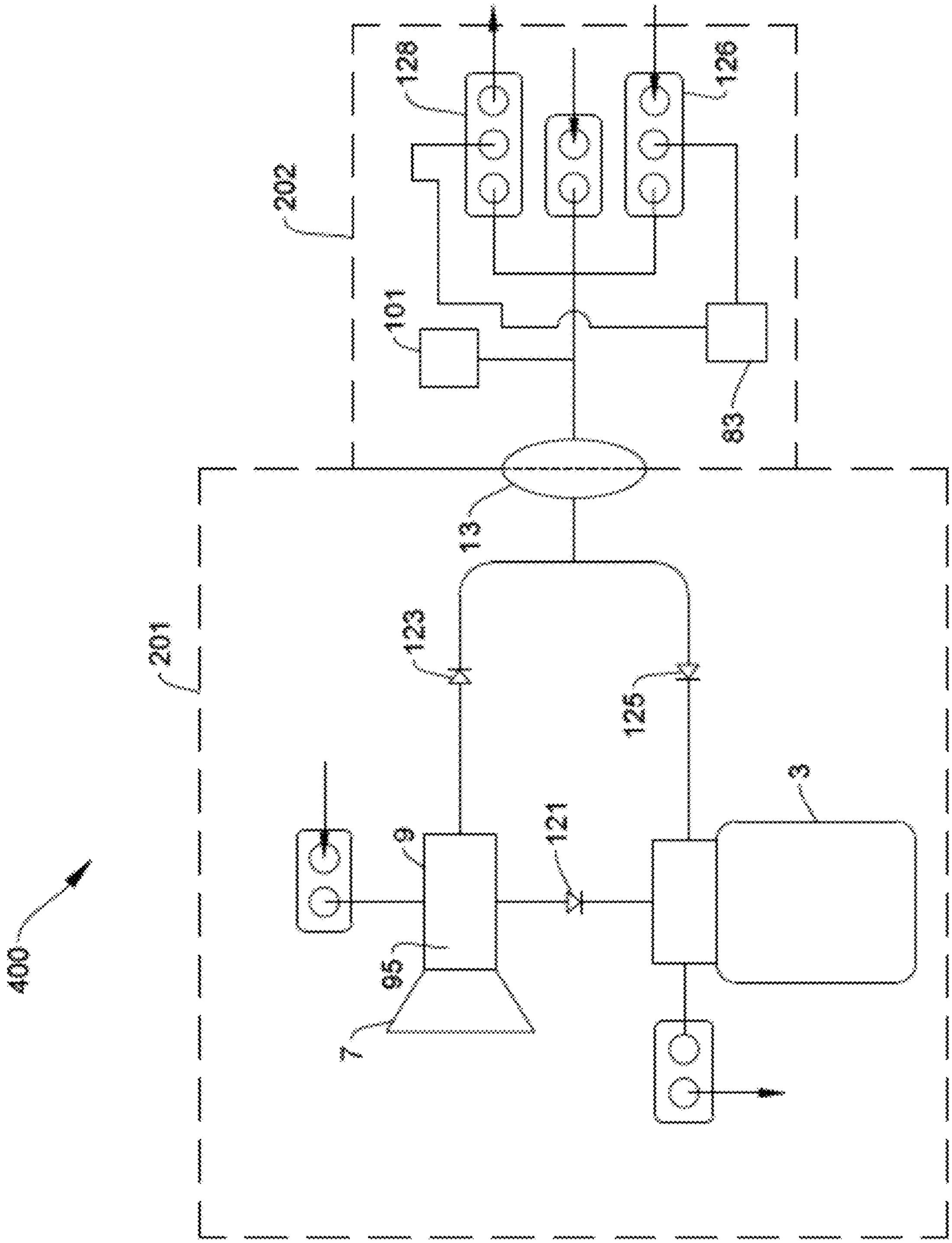
101
103
83
83B
83A
111C
133
202
111A
111B
111
13
300
9
95
201
7
37
3

FIGURE 11



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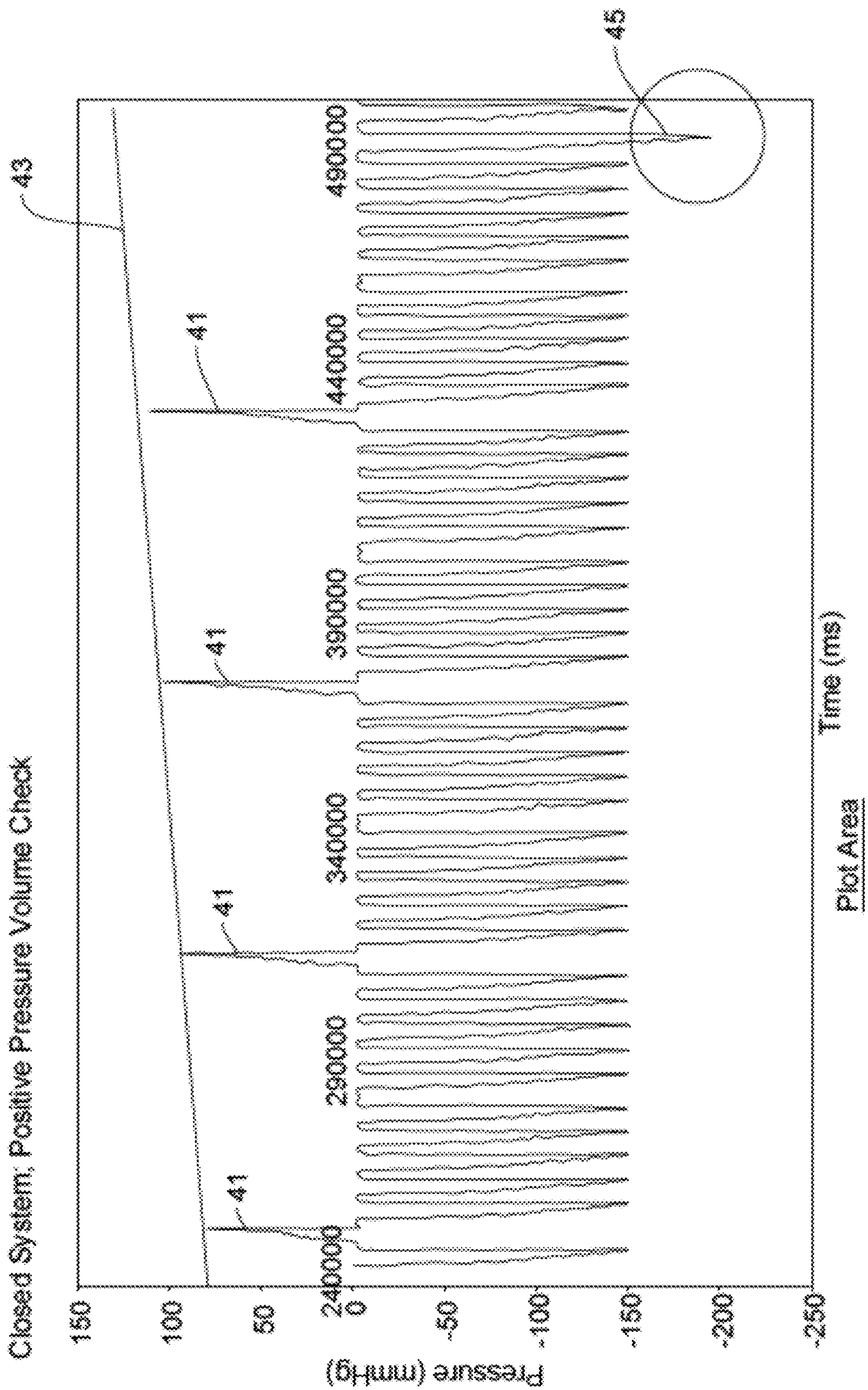

Closed System; Positive Pressure Volume Check
Pressure (mmHg)
150
100
50
0
-50
-100
-150
-200
-250
240000
290000
340000
390000
440000
490000
Time (ms)
Plot Area
41
41
41
41
43
45

FIGURE 13

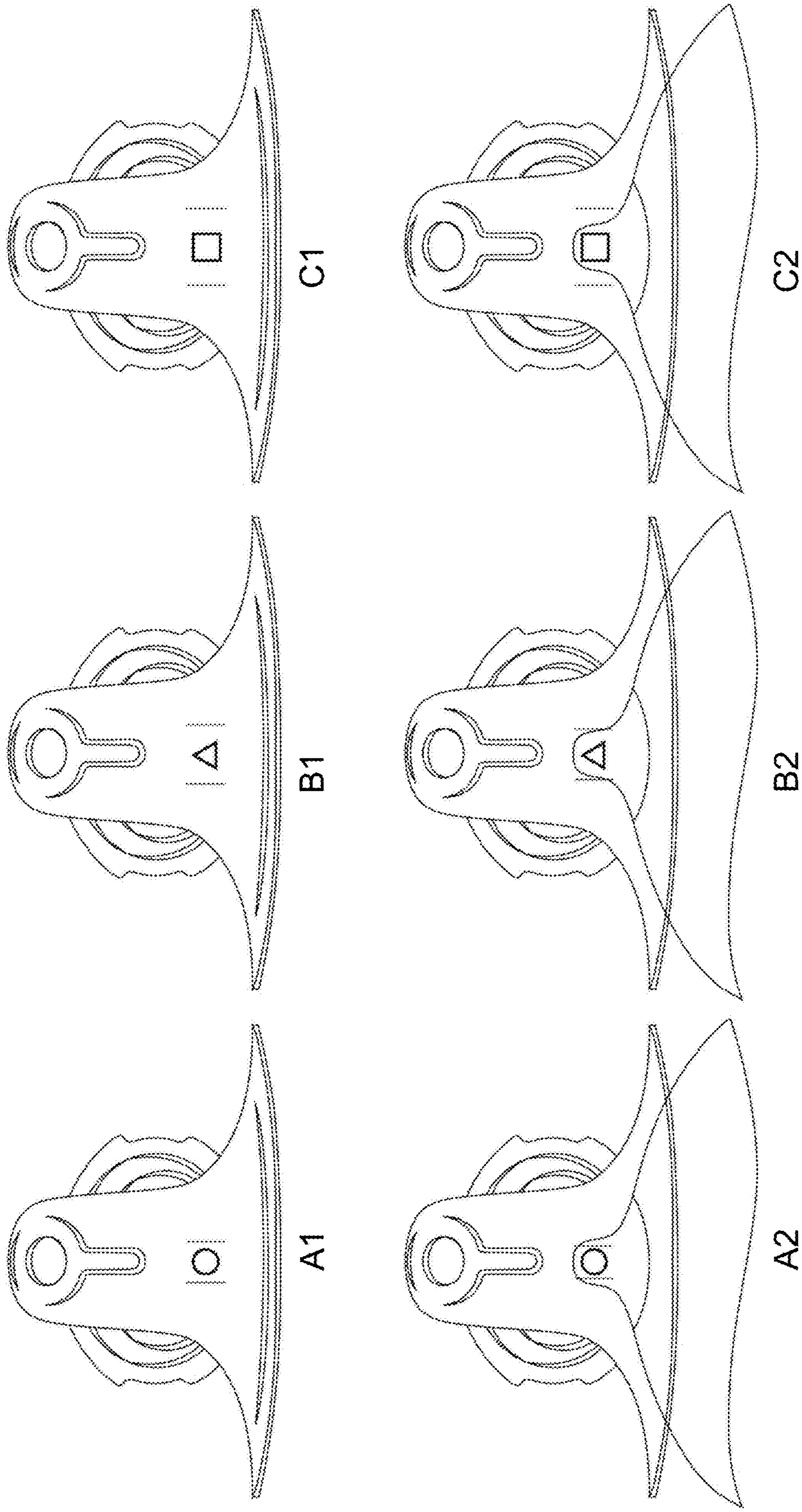
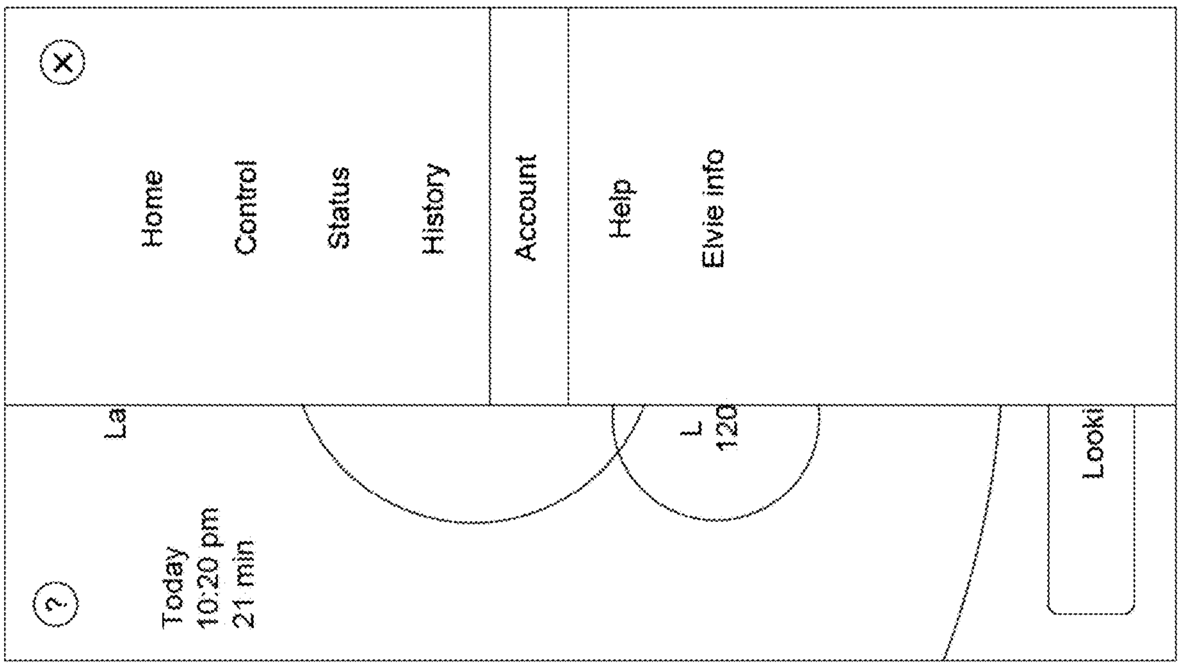


FIGURE 14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Control
Status
History
Account
Help
Elvie info
Today
10:20 pm
21 min
120

FIGURE 15

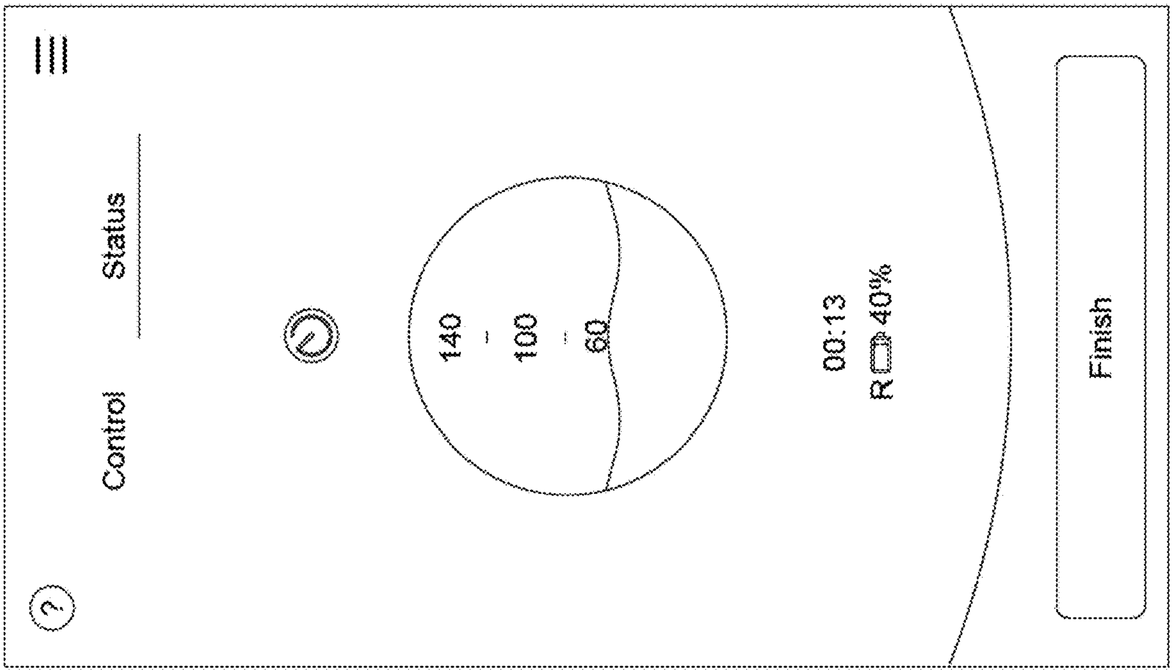

FIGURE 16

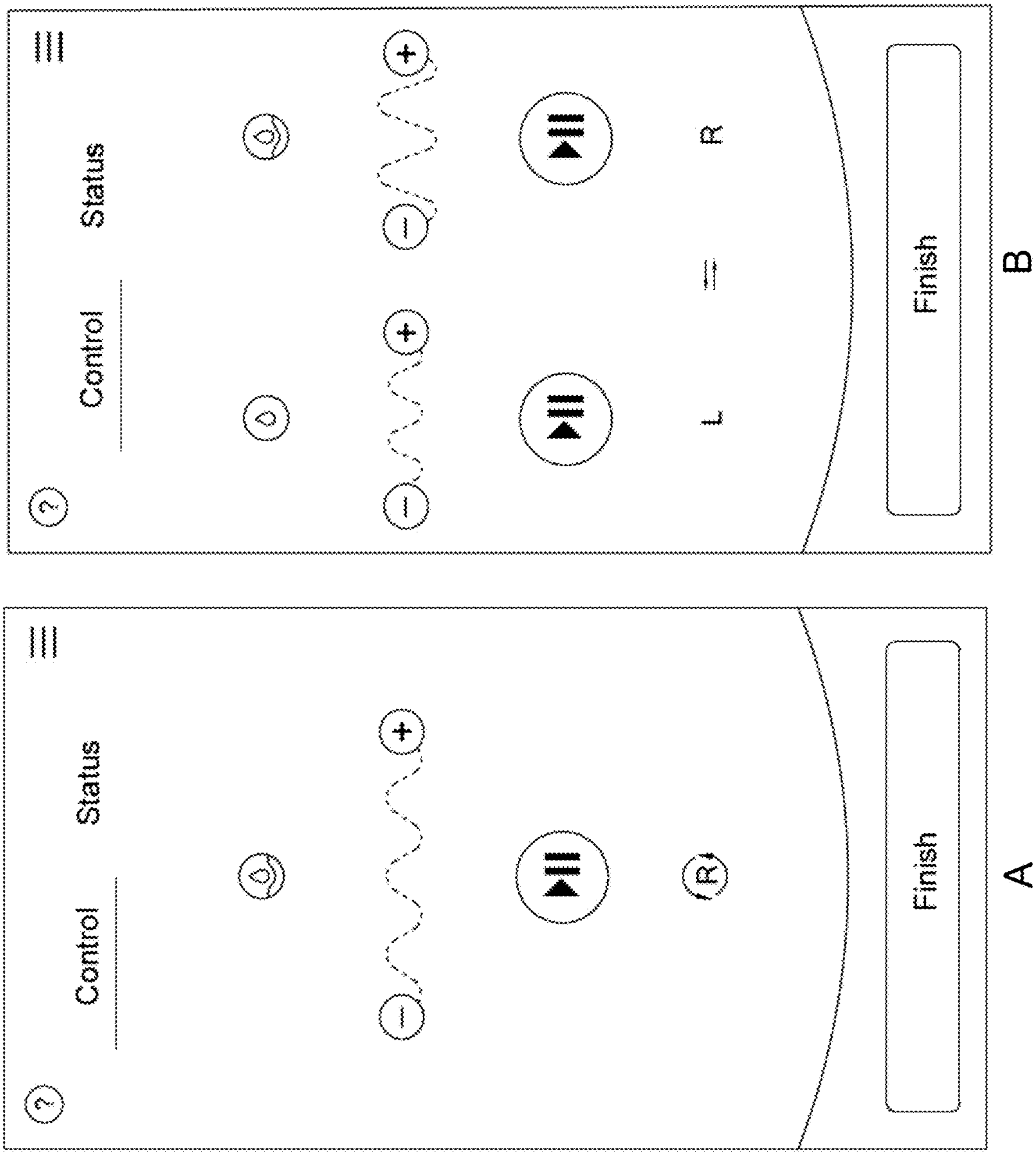

FIGURE 17

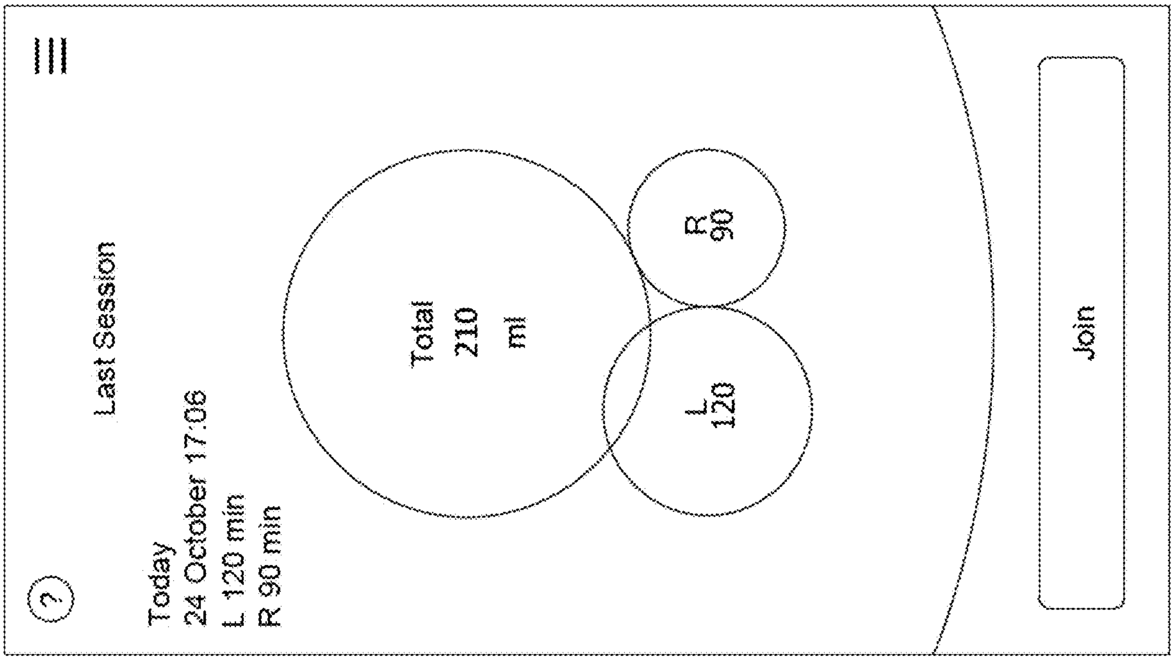
?
Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
ml
R
90
L
120
Join

FIGURE 18

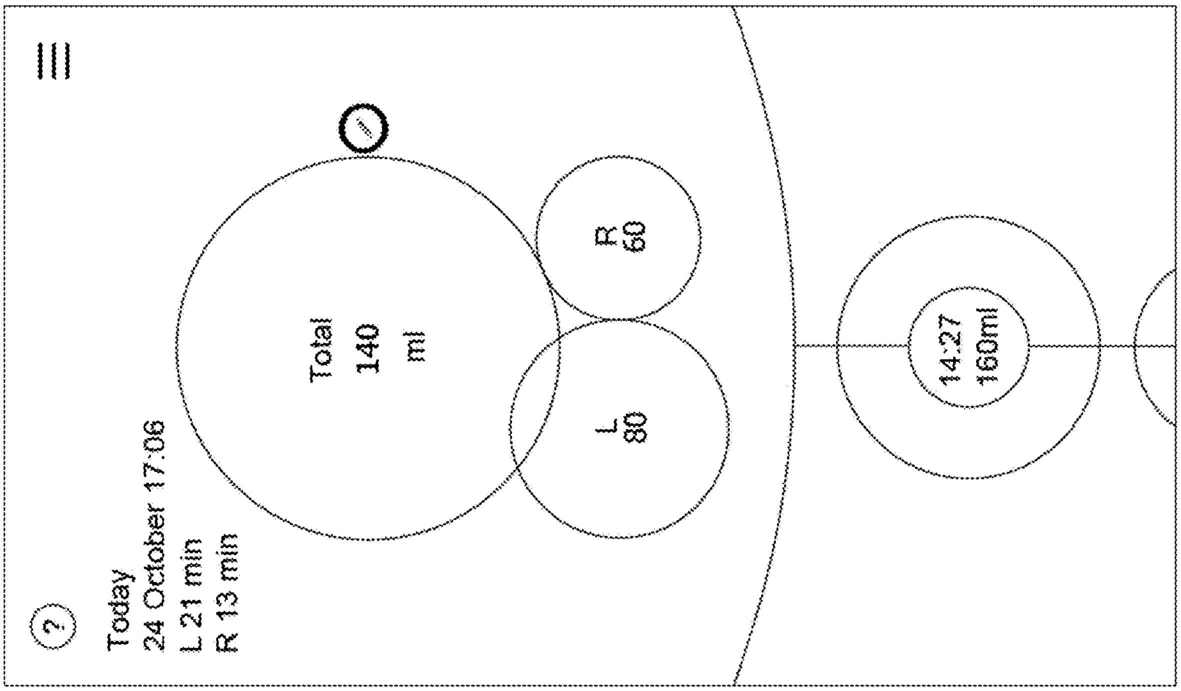
Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
R
60
L
80
14:27
160ml

FIGURE 19

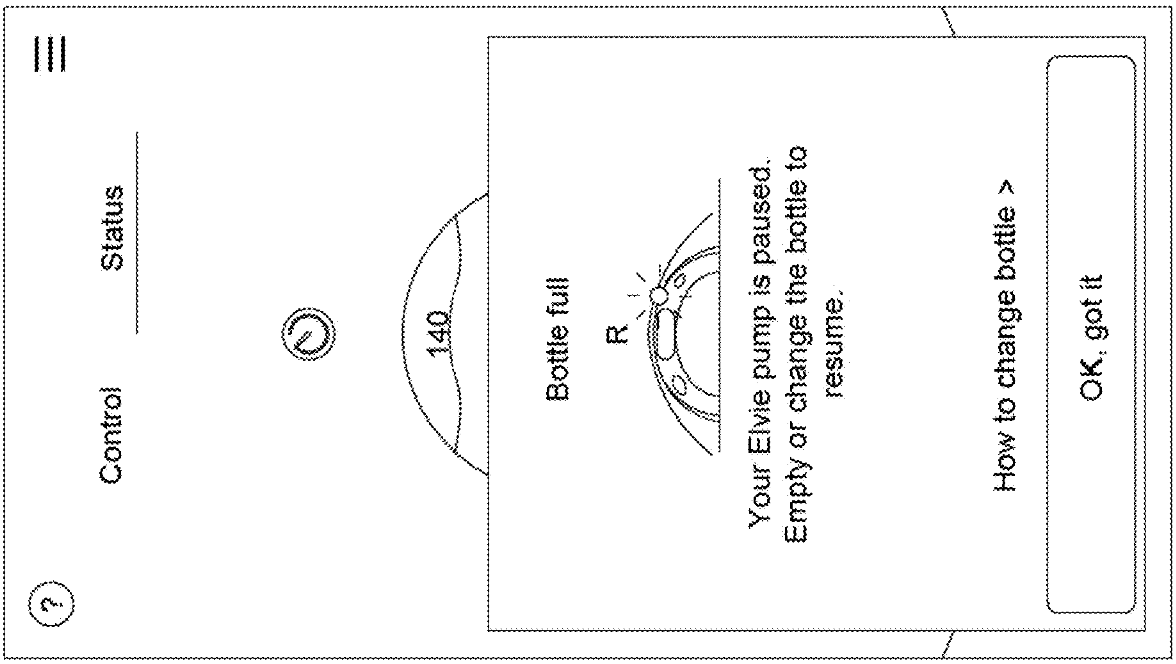
Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to
resume.
How to change bottle >
OK, got it

FIGURE 20

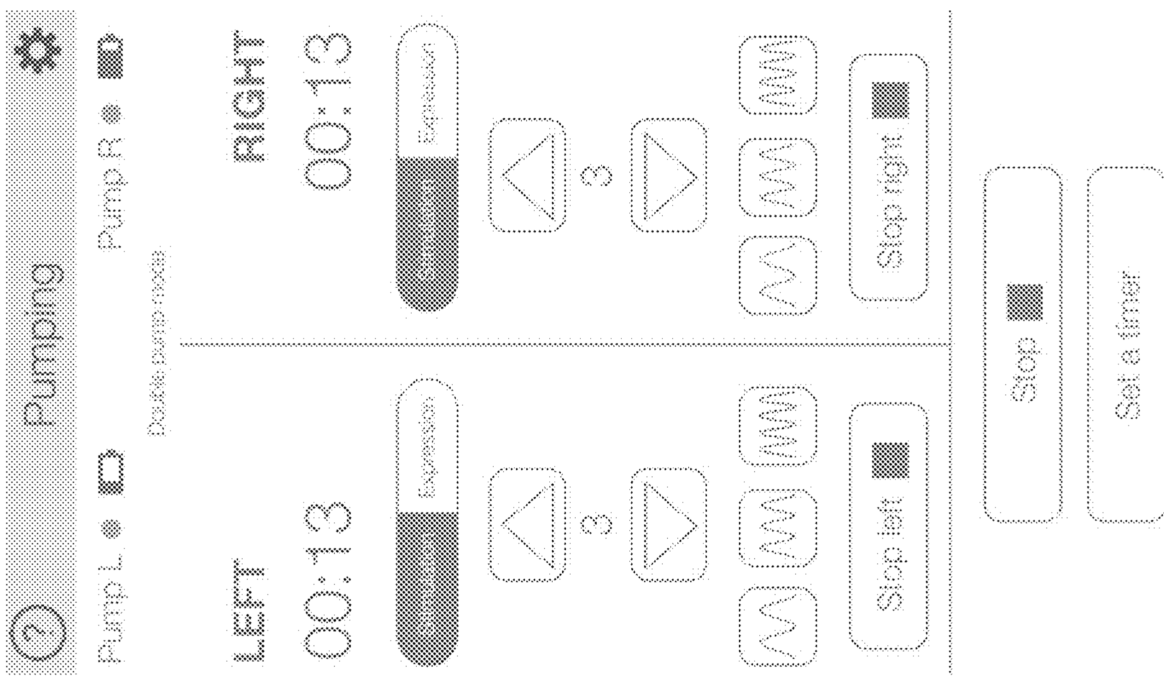
Pumping
Pump L
Pump R
Double pump mode
LEFT
RIGHT
00:13
00:13
Expression
Expression
3
3
Stop left
Stop right
Stop
Set a timer

FIGURE 21

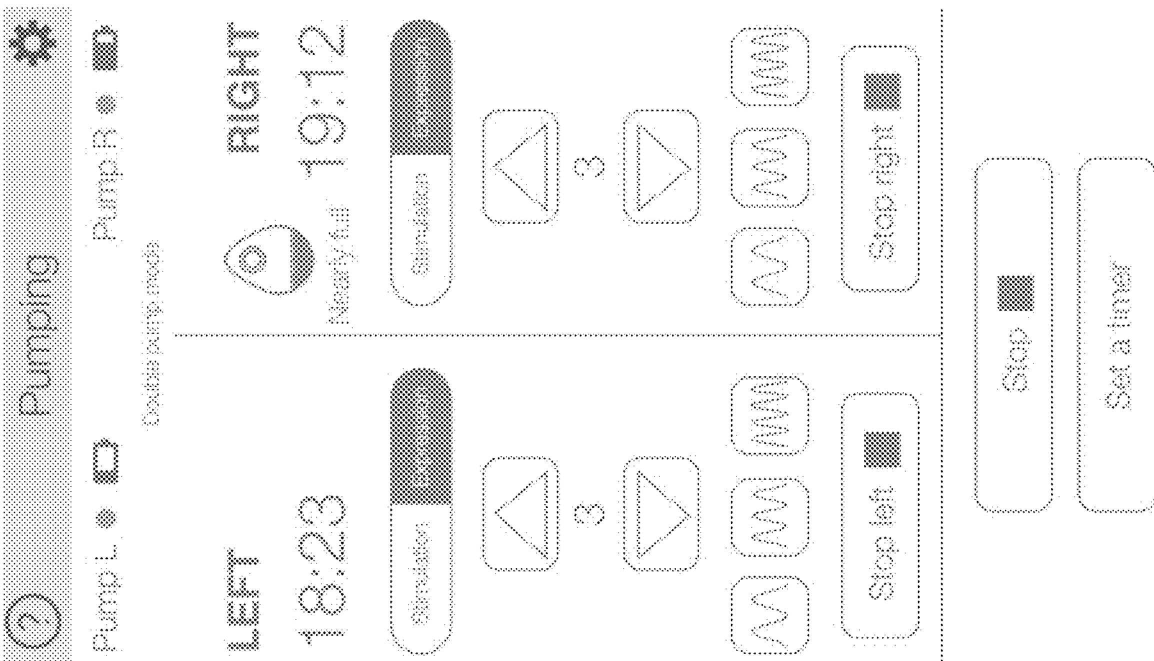
Pumping
Pump L
Pump R
Double pump mode
LEFT
RIGHT
18:23
19:12
Nearly full
Stimulation
Stimulation
3
3
Stop left
Stop right
Stop
Set a timer

FIGURE 22

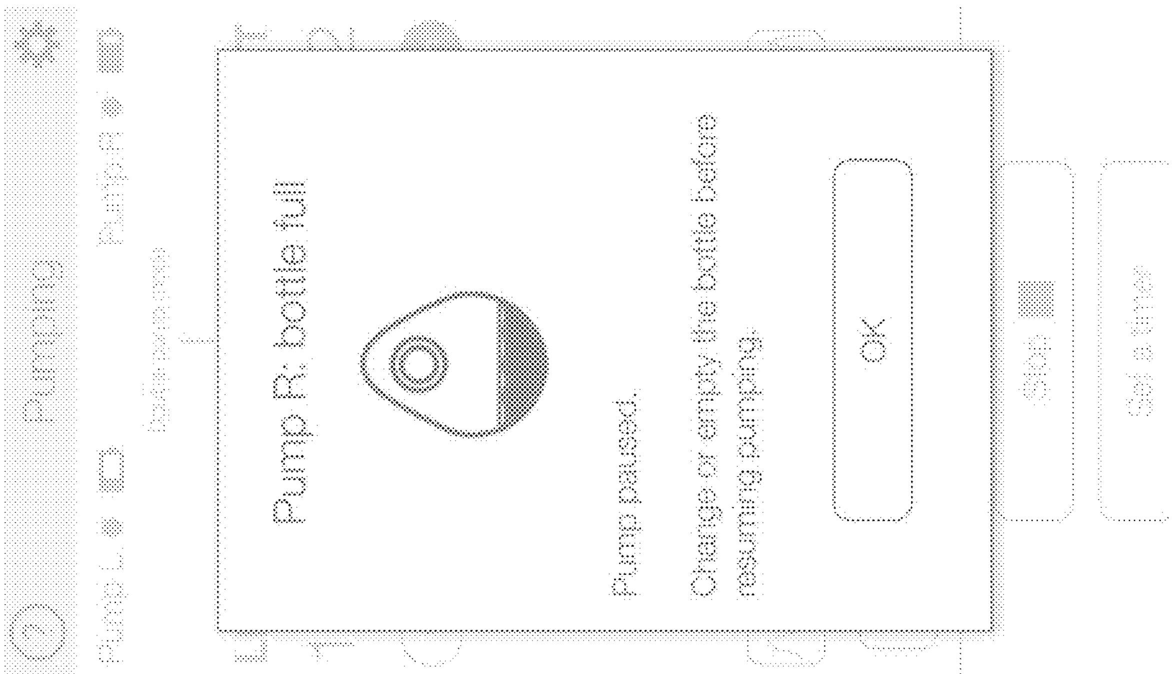
Pumping
Pump L
Pump R
Pump R: bottle full
Pump paused.
Change or empty the bottle before resuming pumping.
OK
Stop
Set a timer

FIGURE 23


Stopped
Pump L
Pump R
Double pump mode
LEFT
21:02
STOPPED
Total volume in bottle:
60 ml
Tick if you emptied or changed the bottle
Resume left
RIGHT
20:38
STOPPED
Total volume in bottle:
65 ml
Tick if you emptied or changed the bottle
Resume right
Resume
End session

FIGURE 24

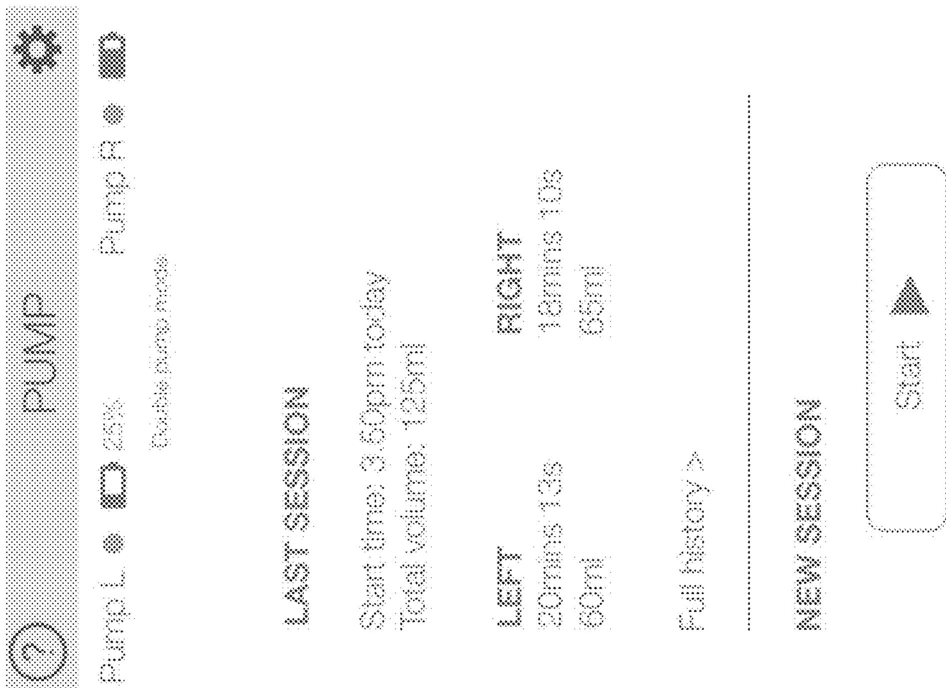
PUMP
Pump L
25%
Double pump mode
Pump R
LAST SESSION
Start time: 3.50pm today
Total volume: 125ml
LEFT
20mins 13s
60ml
RIGHT
18mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

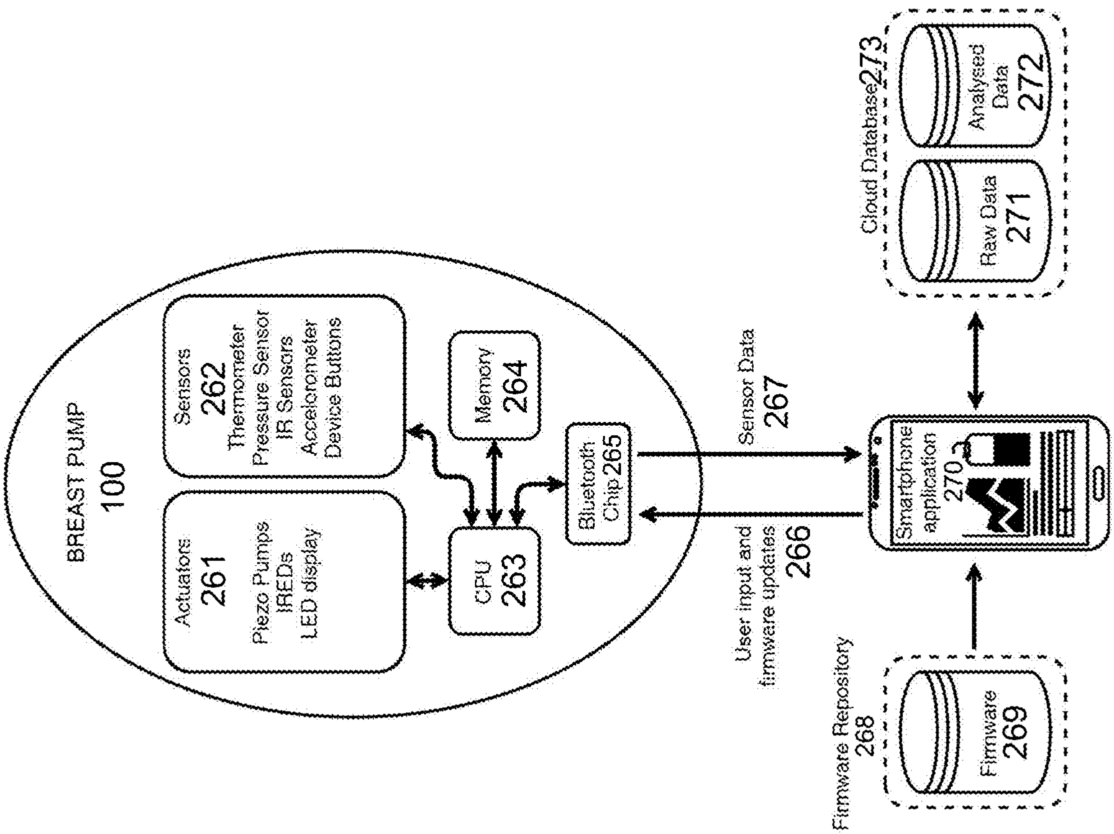
BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelerometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Firmware Repository
268
Firmware
269
Cloud Database 273
Raw Data
271
Analysed
Data
272

FIGURE 26

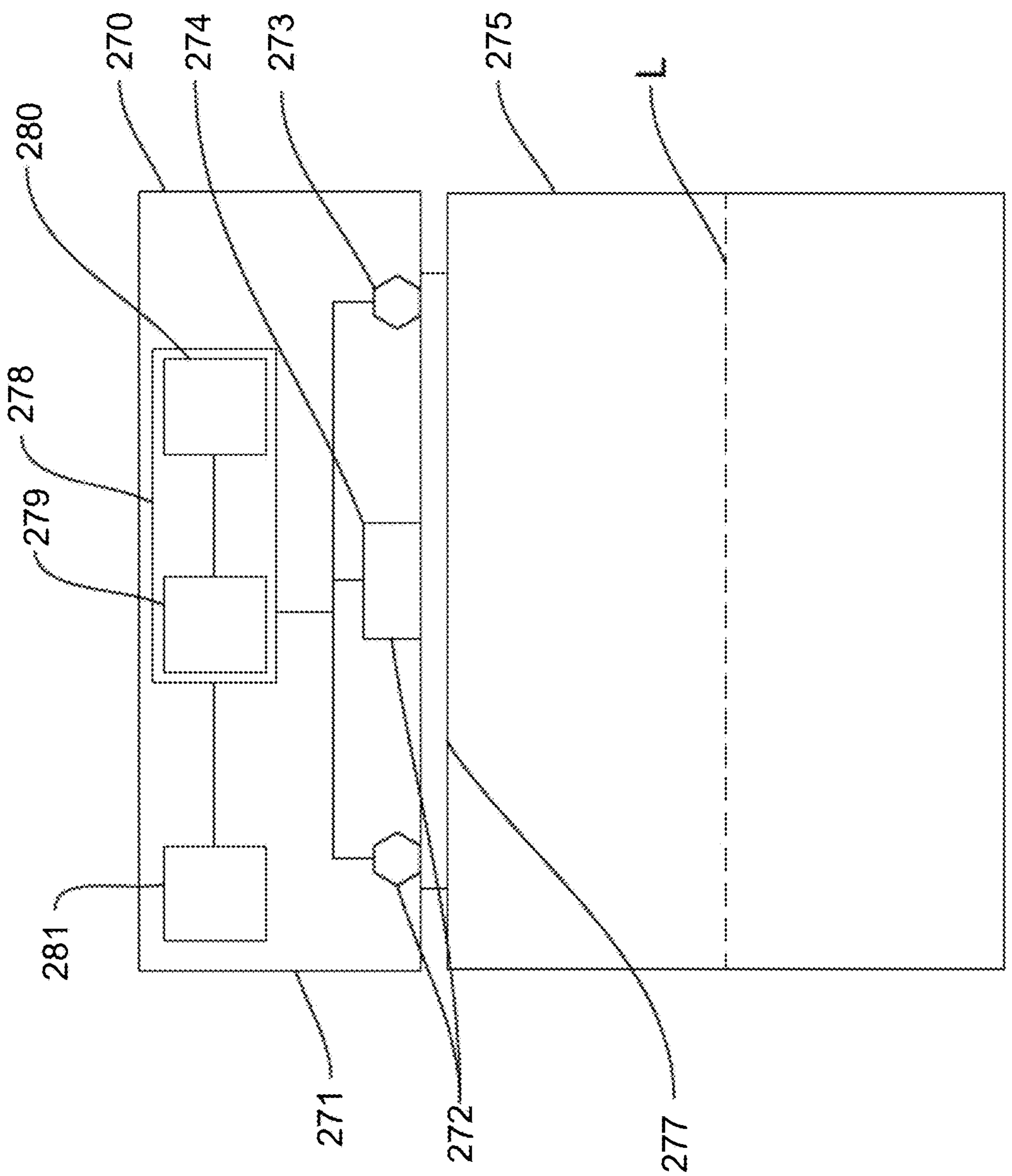

FIGURE 27

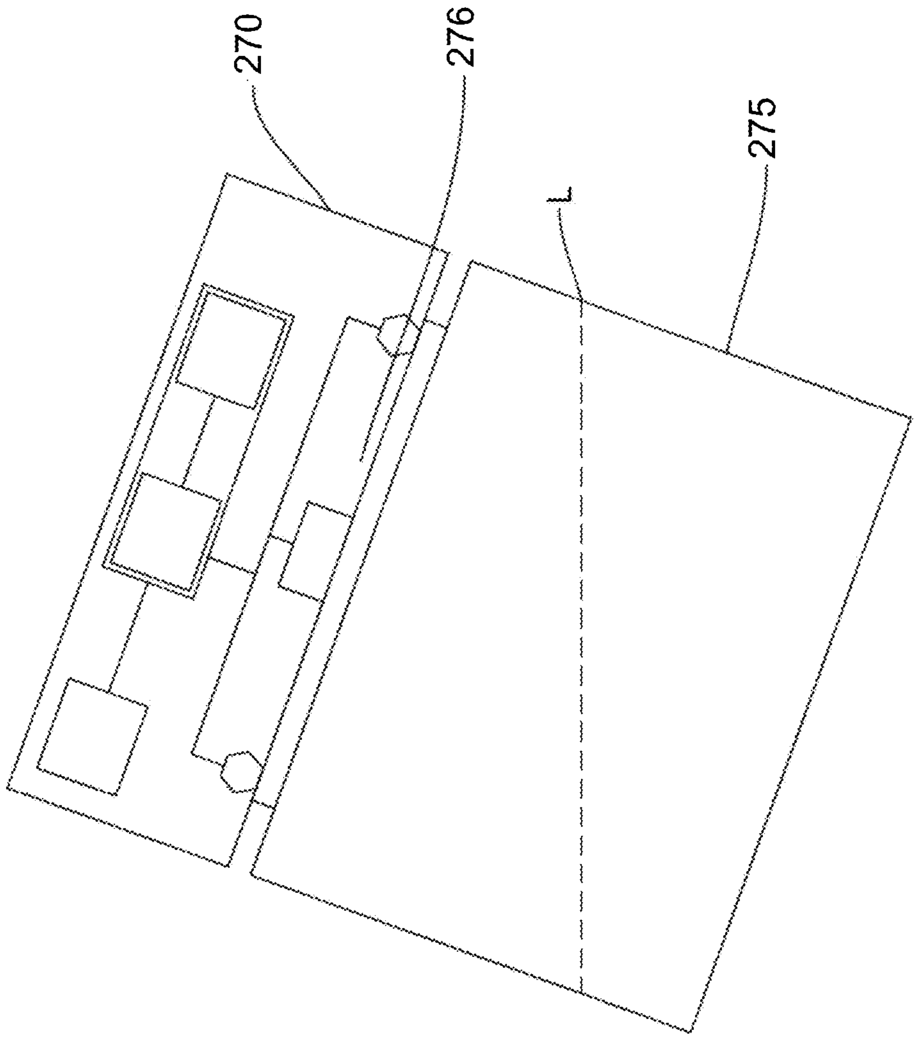

FIGURE 28

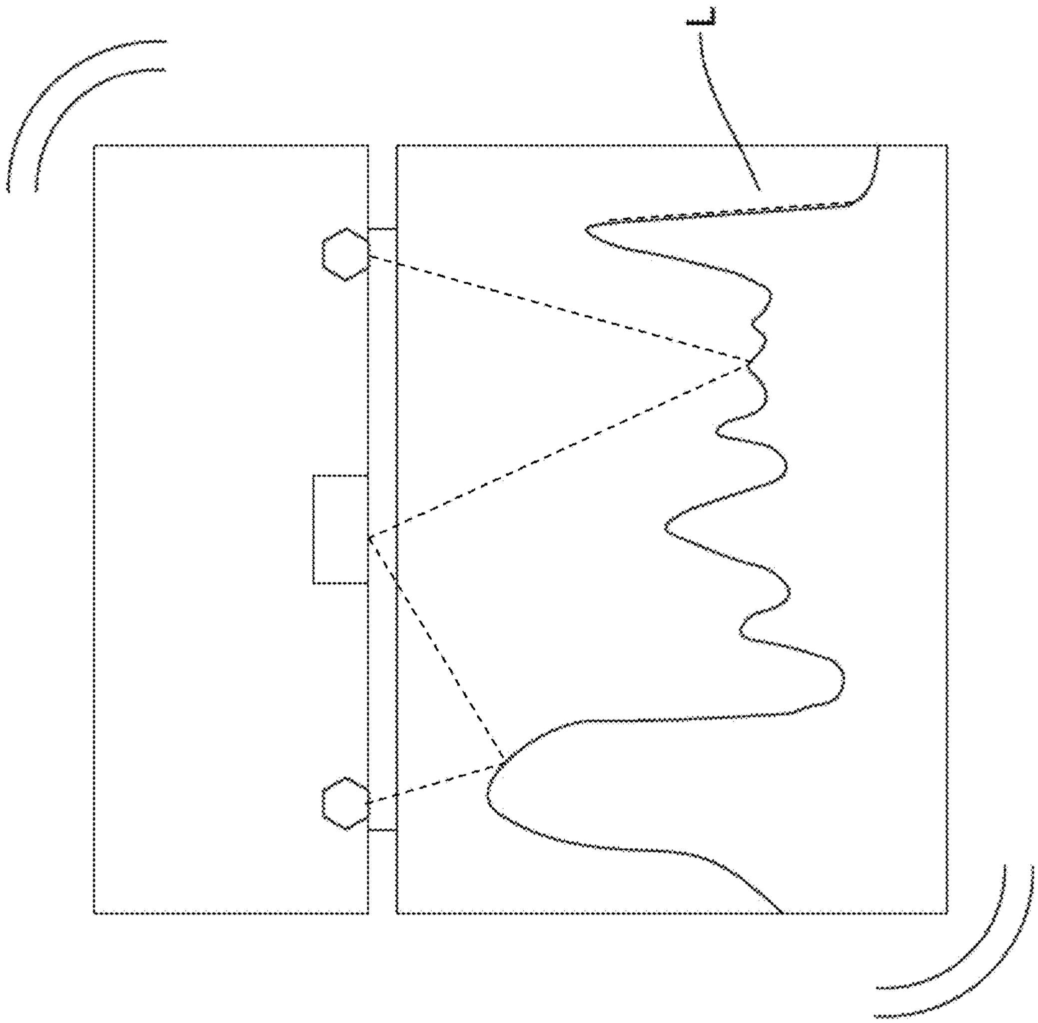

FIGURE 29

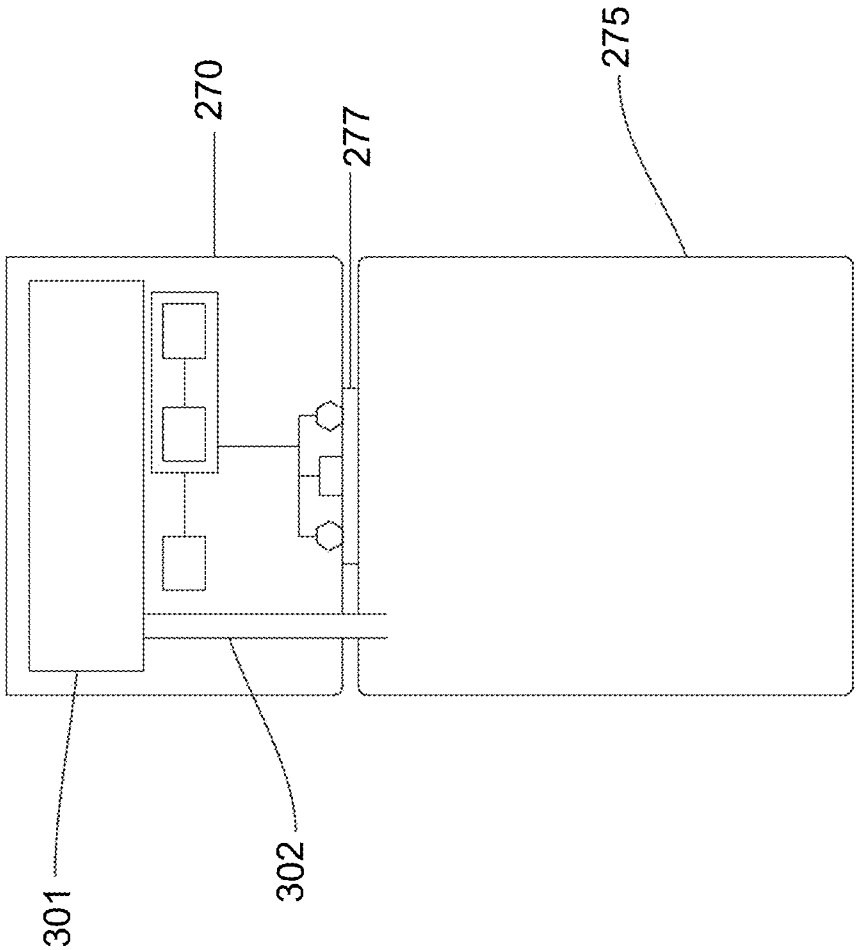

FIGURE 30

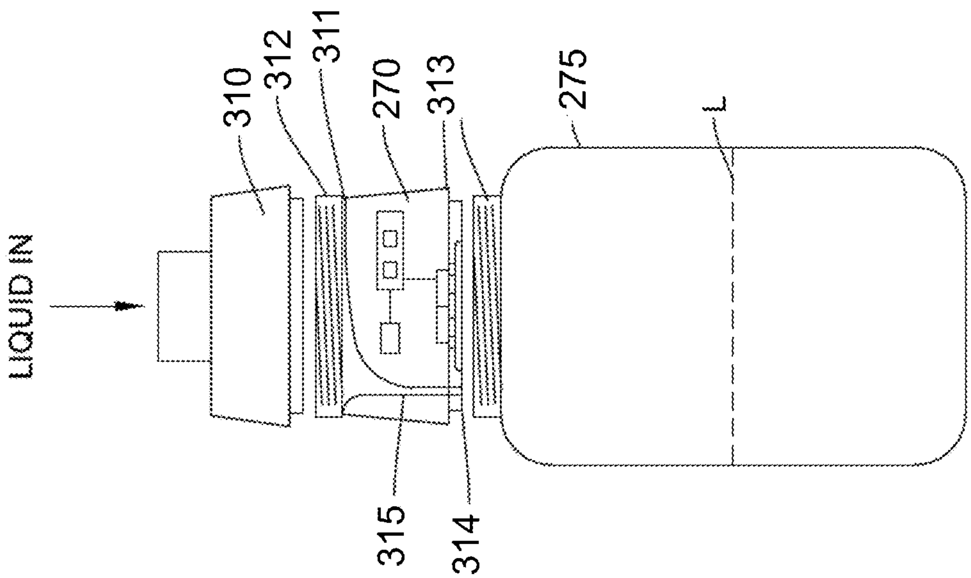

FIGURE 31

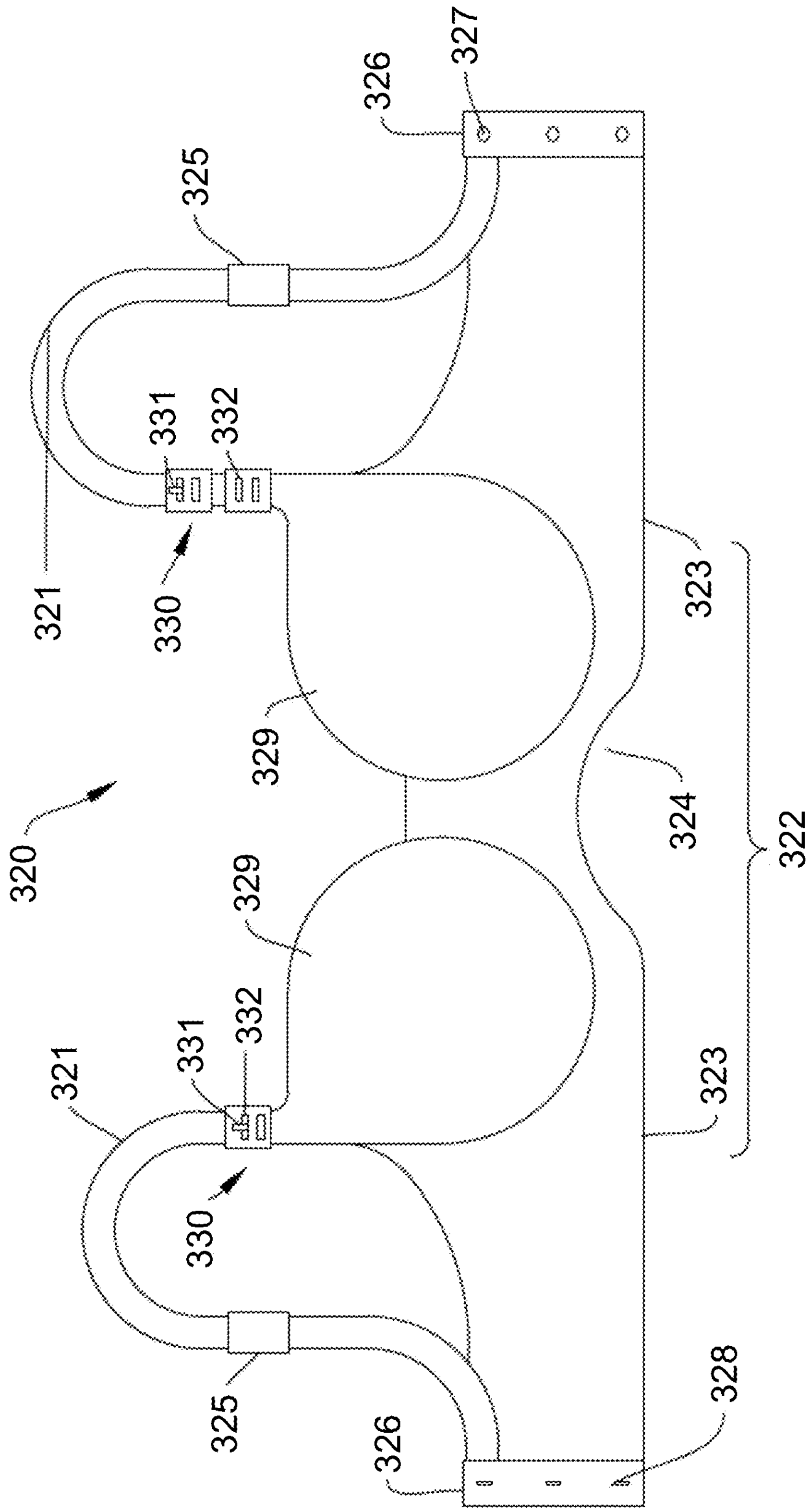
327
326
325
331
332
321
330
323
329
324
320
322
329
332
331
321
323
330
325
326
328

FIGURE 32

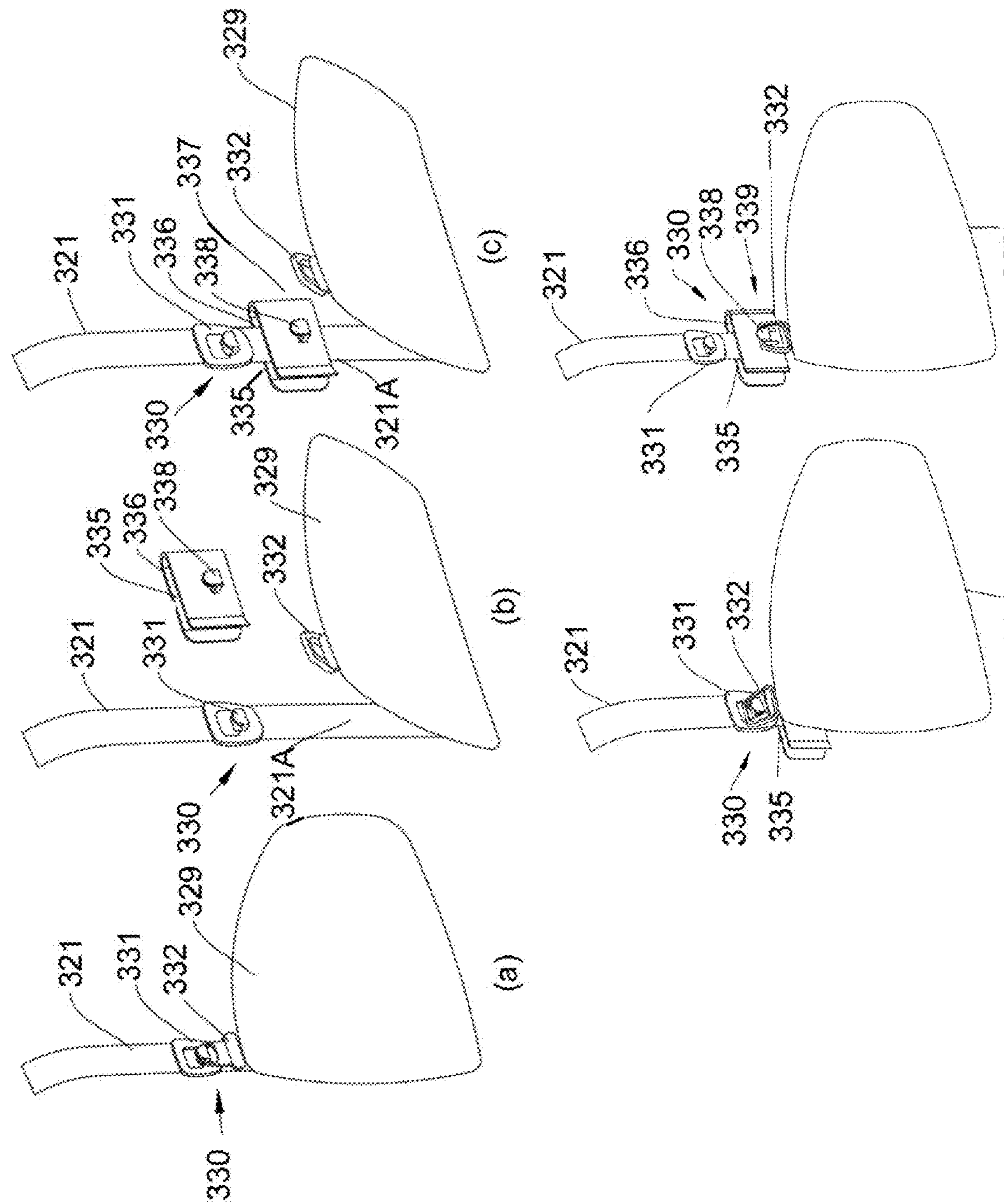

FIGURE 33

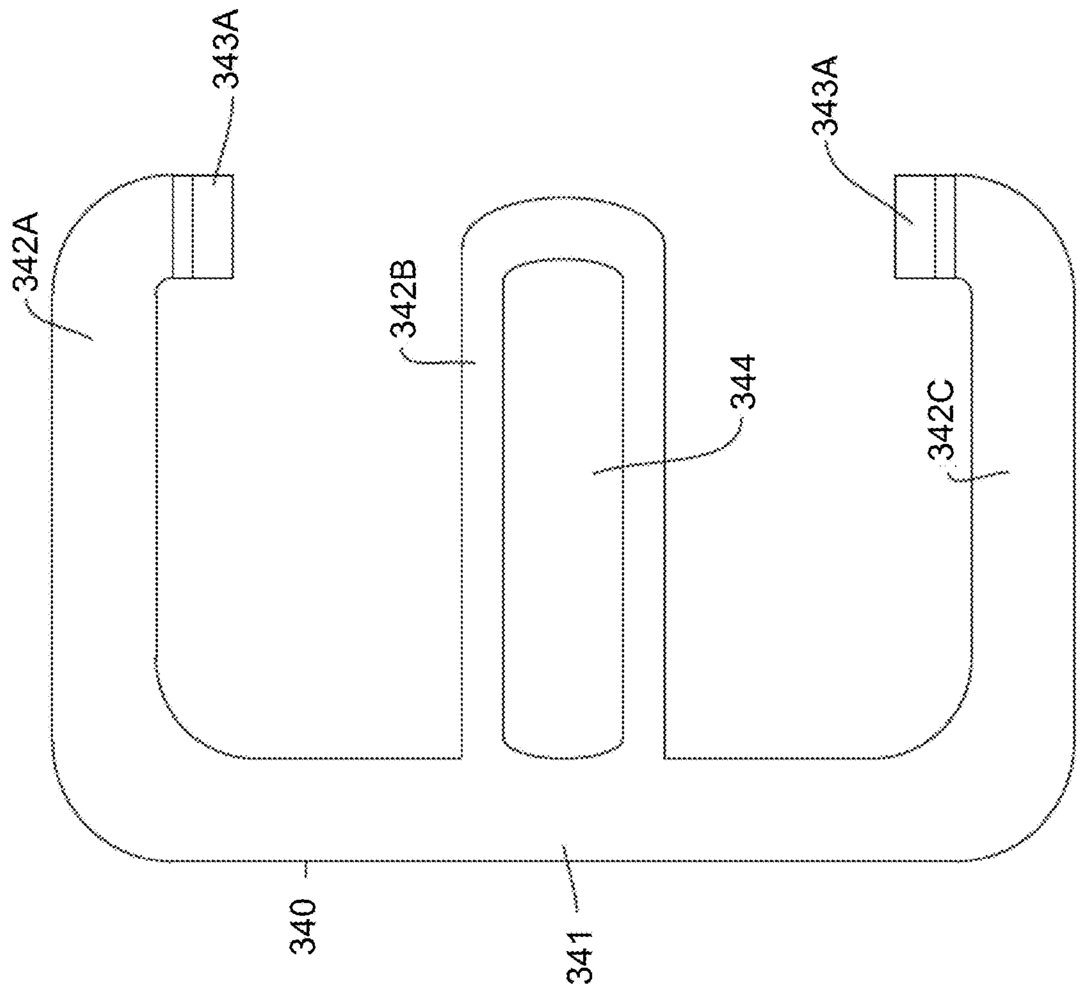

FIGURE 34

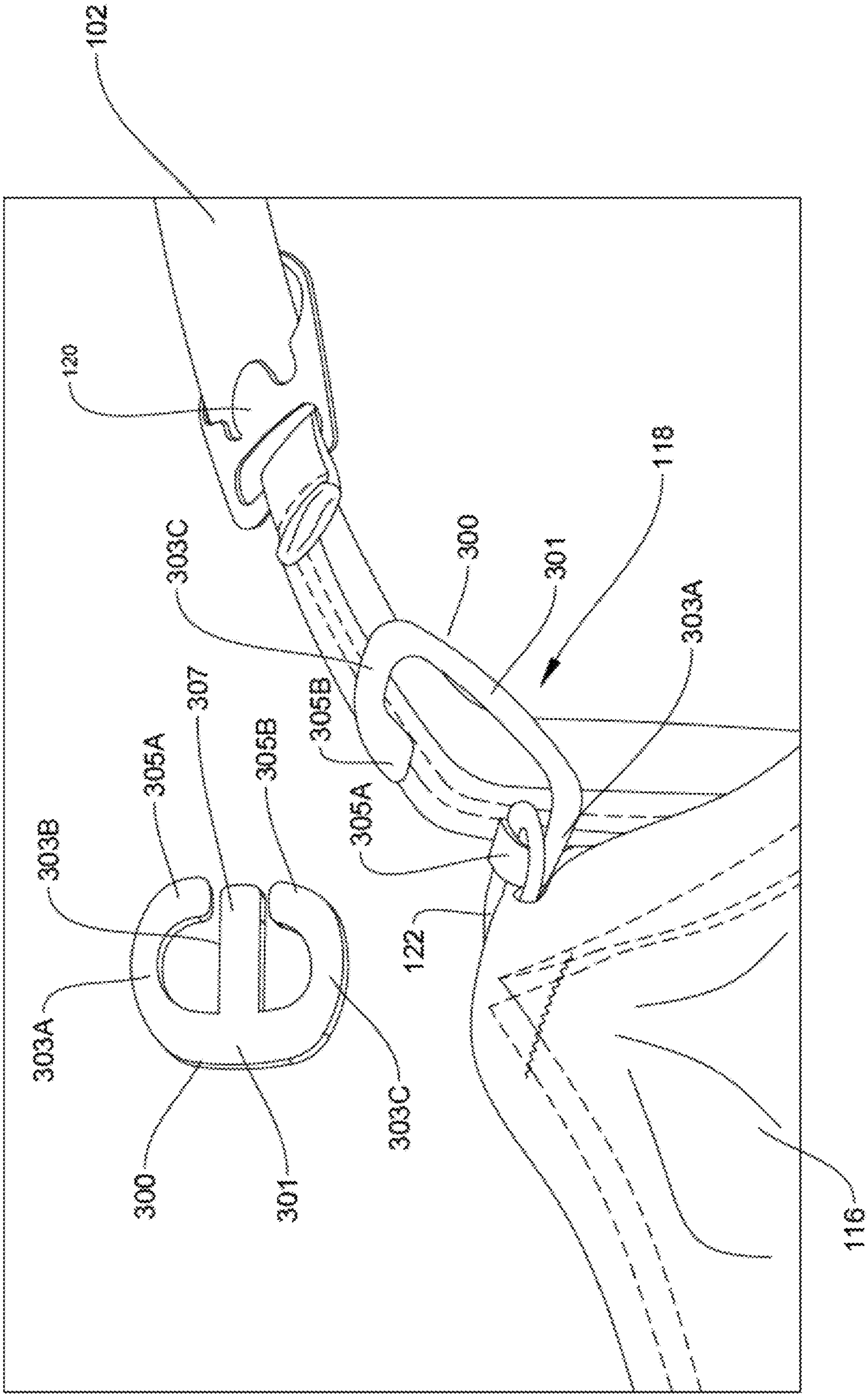
102
120
118
300
301
303C
303A
305B
305A
307
305A
305B
303B
122
303A
303C
300
301
116

FIGURE 35

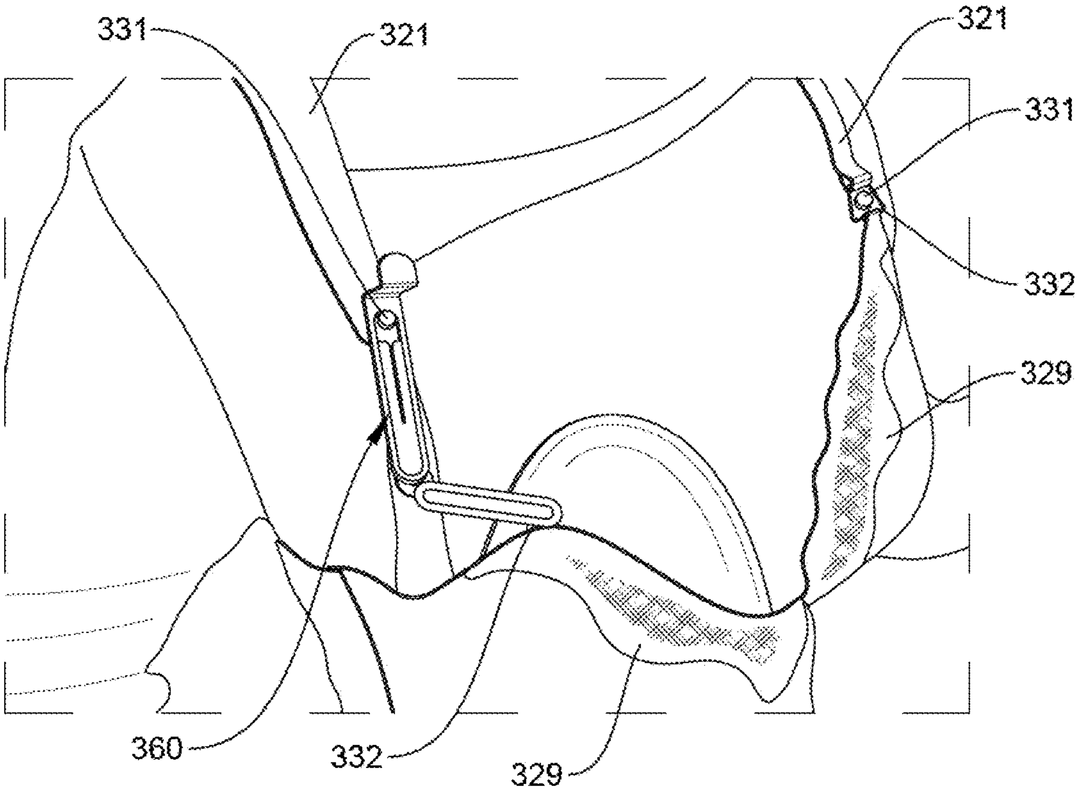

FIGURE 36

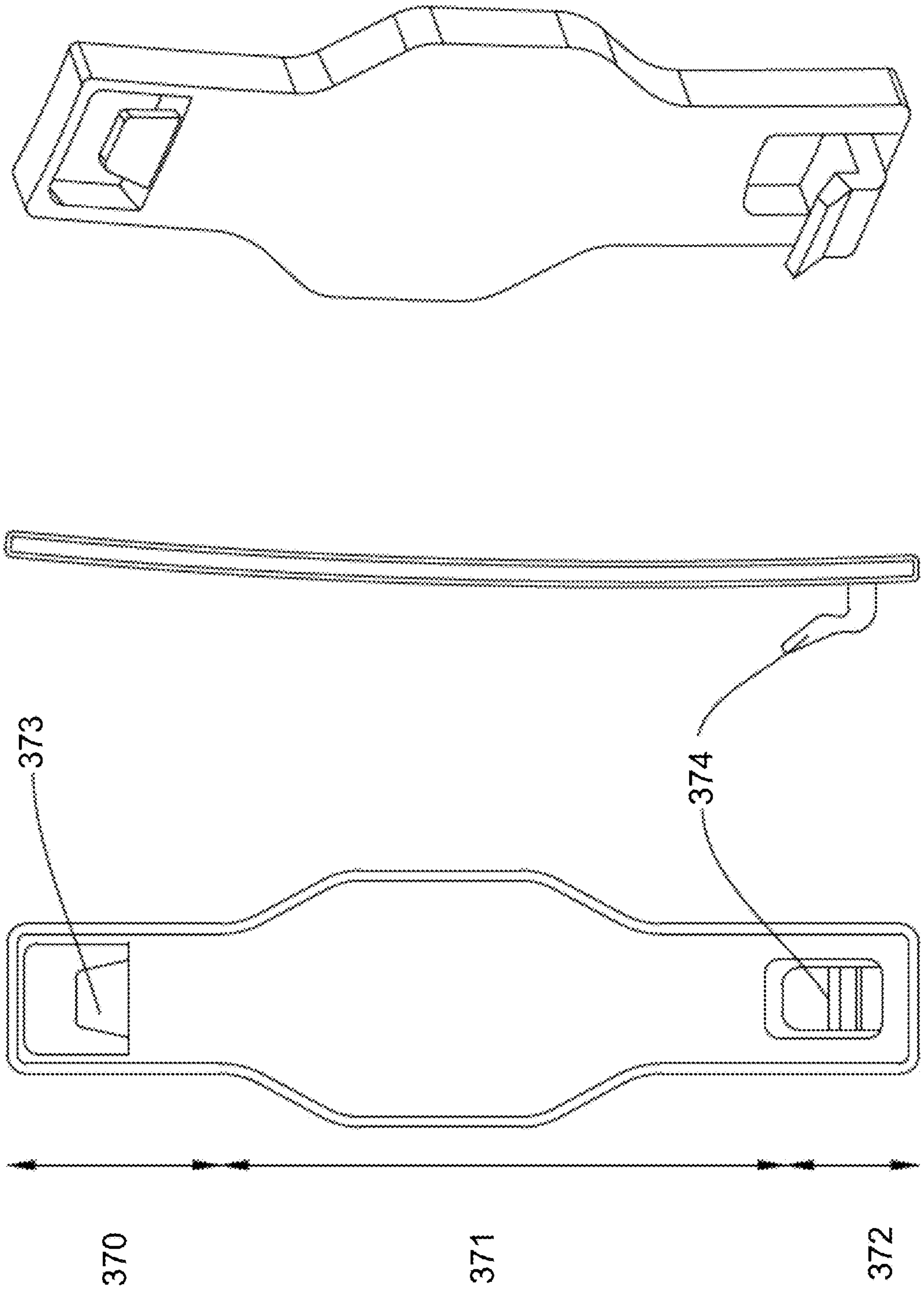

FIGURE 37

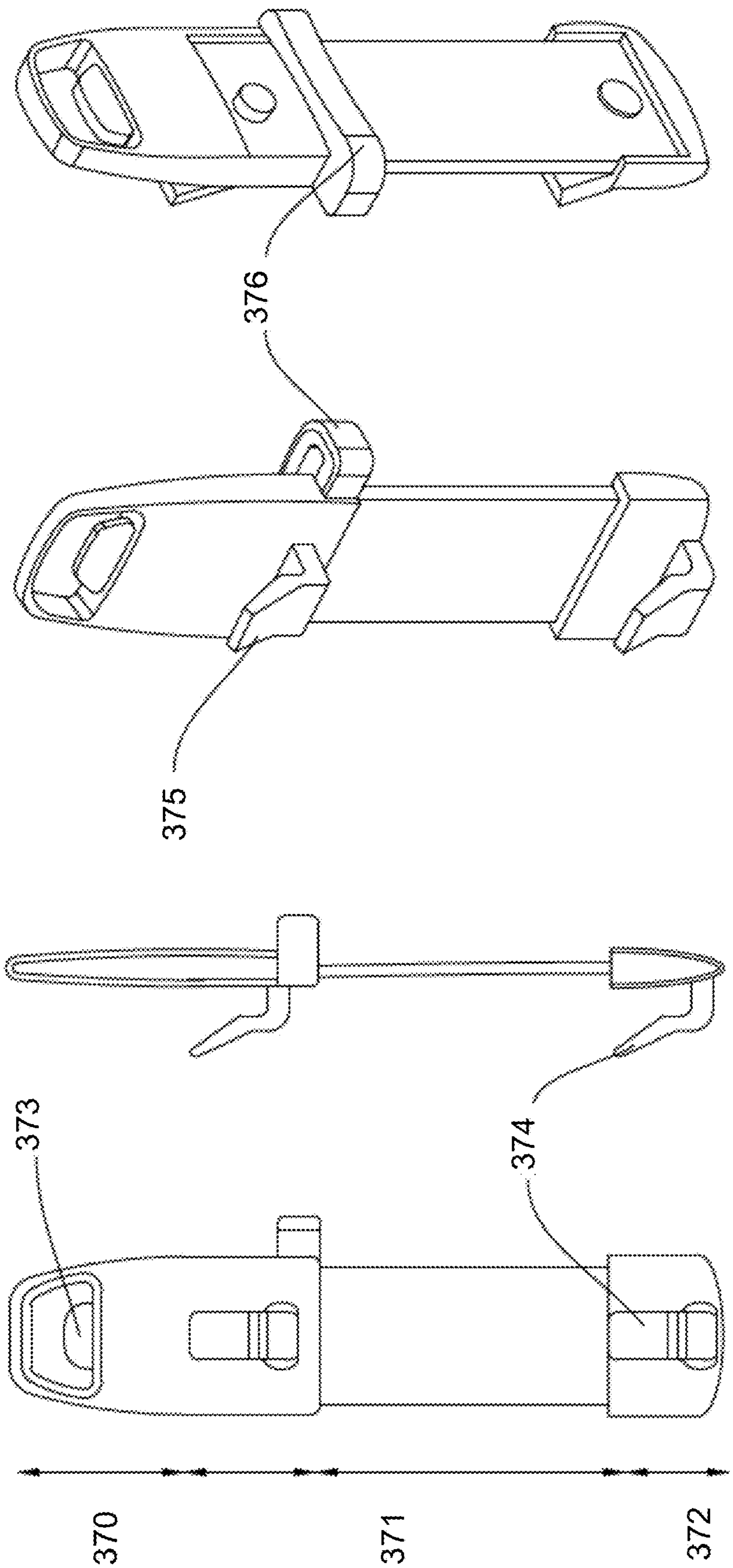

FIGURE 38

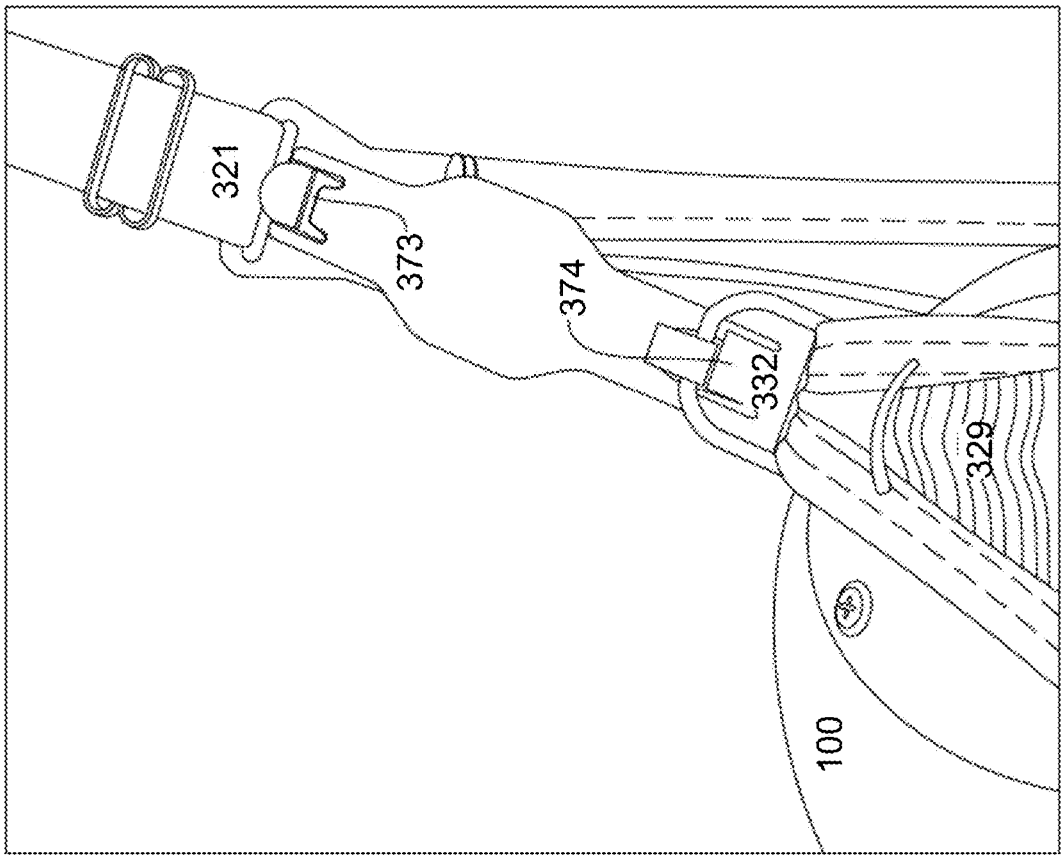

FIGURE 39

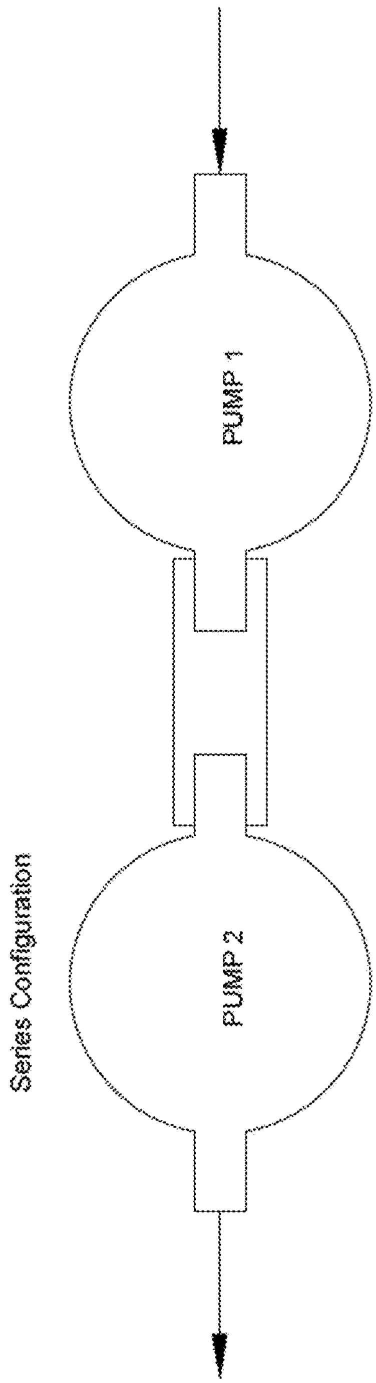

FIGURE 40

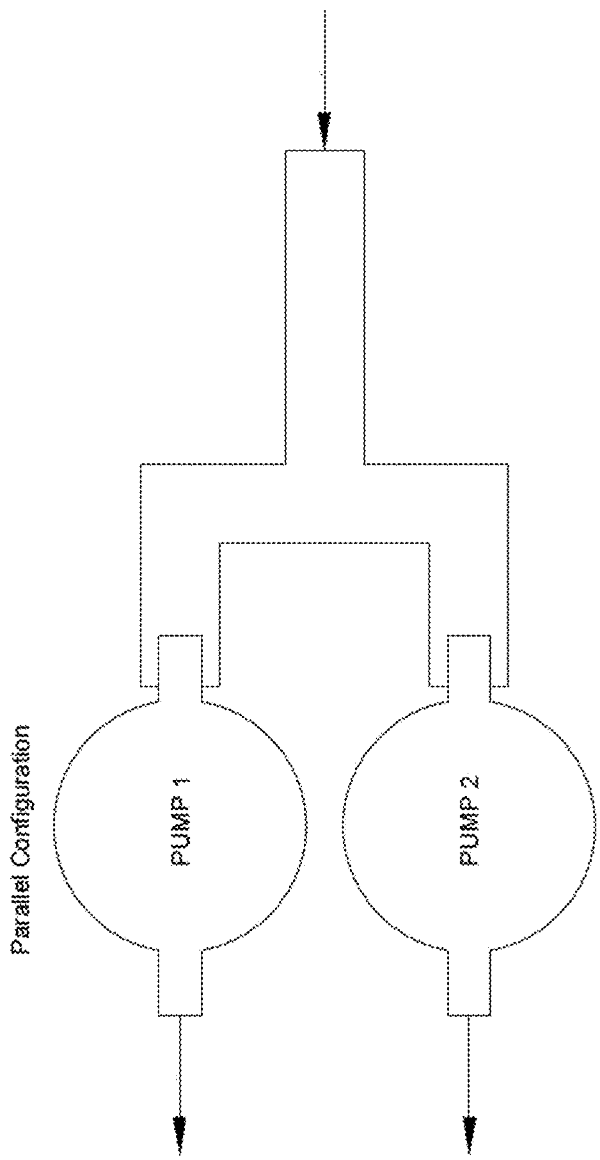

FIGURE 41

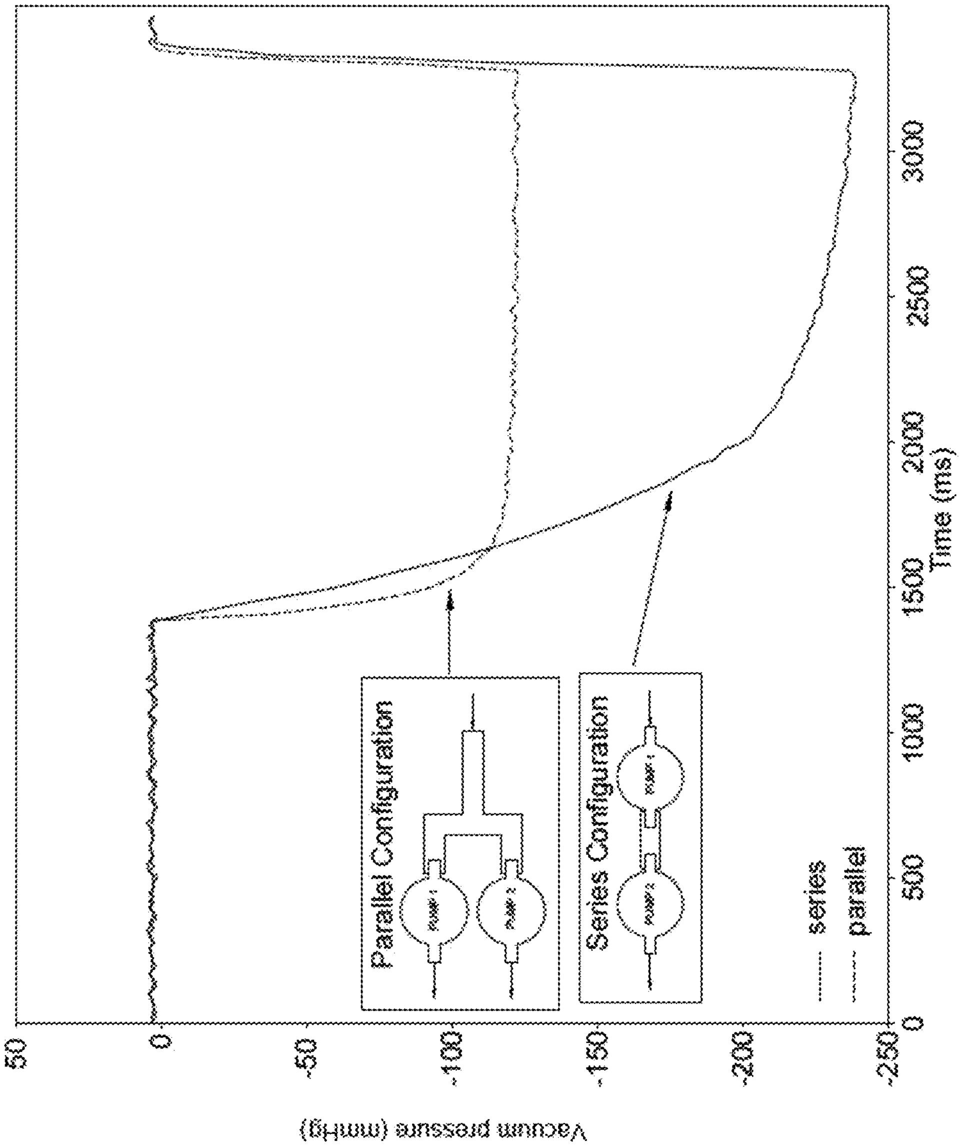
Parallel Configuration
Series Configuration
series
parallel
Time (ms)
Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
500
1000
1500
2000
2500
3000

FIGURE 42

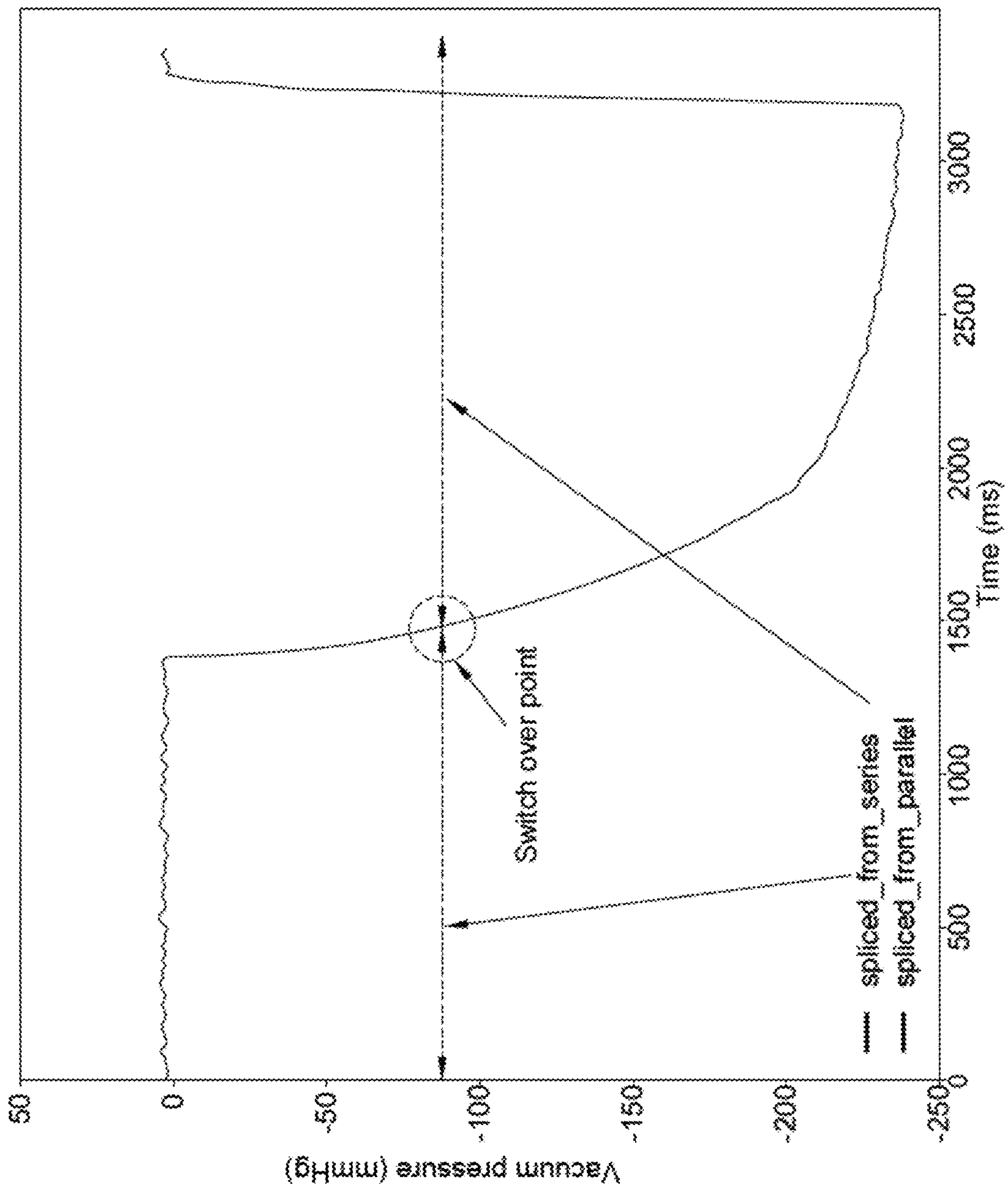
Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
Time (ms)
0
500
1000
1500
2000
2500
3000
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

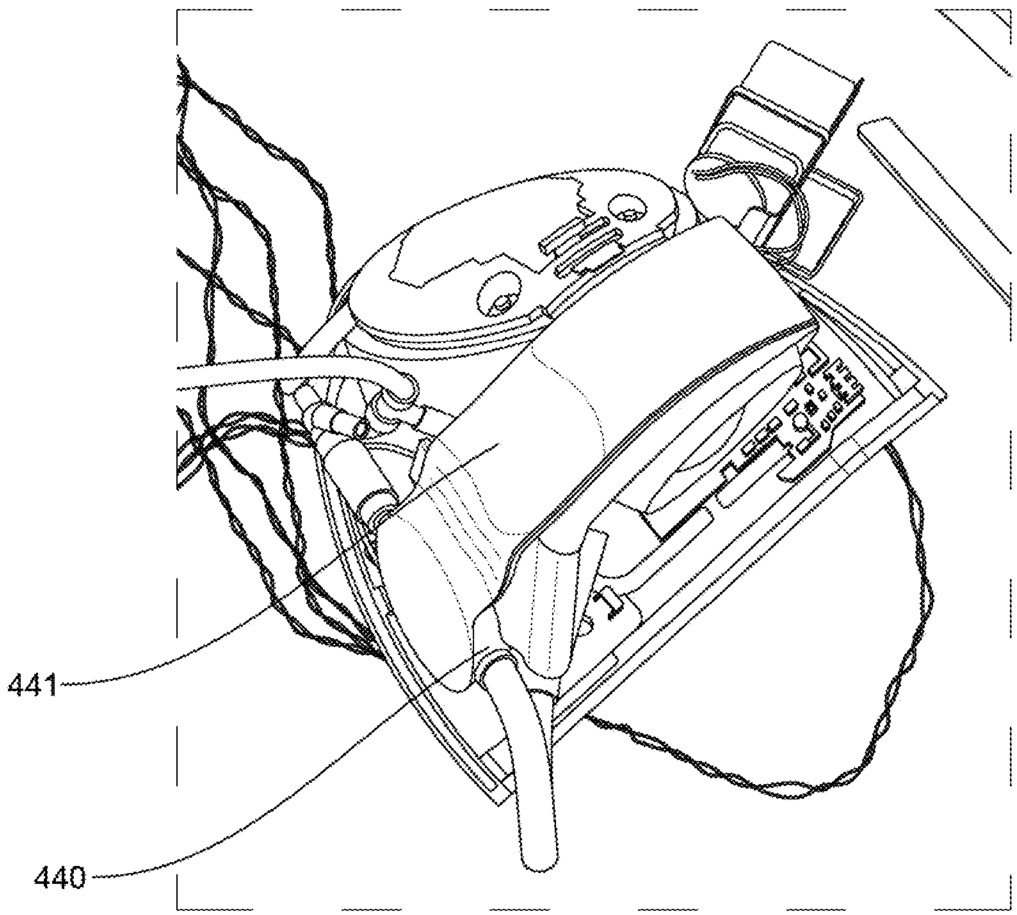

FIGURE 44

BREAST PUMP SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. application Ser. No. 17/181,057, filed on Feb. 22, 2021, which is a U.S. application Ser. No. 16/009,547, filed on Jun. 15, 2018, which is based on, and claims priority to, GB Application No. 1709561.3, filed Jun. 15, 2017; GB Application No. 1709564.7, filed on Jun. 15, 2017; GB Application No. 1709566.2, filed on Jun. 15, 2017; and GB Application No. 1809036.5, filed on Jun. 1, 2018, the entire contents of each of which being fully incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior Art Related to Breast Pump Systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large

freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult for a user to extract all of their milk from the bag, due to the small cut opening that is needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art Related to Liquid Measurement Systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk bottle is not always pos-

sible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art Related to Bra Clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in U.S. Pat. No. 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra; a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

FIG. **1** is a front view of an assembled breast pump system.

FIG. **2** is a rear view of the assembled breast pump system of FIG. **1**.

FIG. **3** is a front view of a partially disassembled breast pump system.

FIG. **4** is a rear view of the partially disassembled breast pump system of FIG. **3**.

FIG. **5** is a front view of a further partially disassembled breast pump system.

FIG. **6** is a rear view of the further partially disassembled breast pump system of FIG. **5**.

FIG. **7** is a front view of the breast pump system of FIG. **1**, with the outer shell translucent for ease of explanation.

FIG. **8** is a further front view of the breast pump system of FIG. **1**, with the front of the outer shell removed for ease of explanation.

FIG. **9** is a schematic view of a nipple tunnel for a breast shield.

FIG. **10** is a schematic of a pneumatic system for a breast pump system.

FIG. **11** is a schematic of an alternative pneumatic system for a breast pump system.

FIG. **12** is a schematic of a further alternative pneumatic system for a breast pump system.

FIG. **13** is a graph depicting measured pressure in the breast pump system of FIG. **12** over time.

FIG. **14** shows schematics for breast shield sizing and nipple alignment.

FIG. **15** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **16** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **17** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **18** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **19** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **20** shows a screenshot of an application running on a connected device.

FIG. **21** shows a screenshot of an application running on a connected device.

FIG. **22** shows a screenshot of an application running on a connected device.

FIG. **23** shows a screenshot of an application running on a connected device.

FIG. **24** shows a screenshot of an application running on a connected device.

FIG. **25** shows a screenshot of an application running on a connected device.

FIG. **26** shows a diagram of a breast pump sensor network,

FIG. **27** shows a sectional view of a device being used to determine the level of liquid in a container;

FIG. **28** shows a sectional view of the device and the container from FIG. **27** being used at a different orientation.

FIG. **29** shows a sectional view of the device and the container from FIG. **27** being used whilst undergoing acceleration.

FIG. **30** shows a sectional view of the device from FIG. **27** being used as part of a breast pump assembly.

FIG. **31** shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

FIG. **32** depicts a prior art design for a maternity bra;

FIG. **33** depicts a clip and clasp being fitted to a maternity bra.

FIG. **34** depicts an alternative clip for adjustment of a maternity bra.

FIG. **35** depicts the alternative clip of FIG. **34**.

FIG. **36** depicts an alternative clip for adjustment of a maternity bra.

FIG. **37** depicts an alternative clip for adjustment of a maternity bra.

FIG. **38** depicts an alternative clip for adjustment of a maternity bra.

FIG. **39** depicts adjustment of the maternity bra of FIG. **37**.

FIG. **40** shows a configuration with two piezo pumps mounted in series.

FIG. **41** shows a configuration of two piezo pumps mounted in parallel.

FIG. **42** shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

FIG. **43** shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

FIG. **44** shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System

Section B: An IR System

Section C: A Bra Clip

Section D: Piezo Pumps and Wearable Devices

Section A: The Elvie™ Breast Pump System

1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to FIG. **1** and FIG. **2**, the assembled breast pump system **100** includes a housing **1** shaped to substantially fit inside a bra. The housing **1** includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing **1**: the breast shield **7** and a milk container **3**. The breast shield **7** and the milk container **3** are directly removable or attachable from the housing **1** in normal use or during normal dis-assembly (most clearly shown in FIG. **5**). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield **7** or the milk container **3**. The breast shield **7** and milk container **3** may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing **1**, breast shield **7** that is holding a flexible diaphragm, and milk container **3** attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing **1**. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container **3**.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it self-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and dis-assembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of discrete parts.

The breast pump system **100** comprises a housing **1** and a milk collection container (or bottle) **3**. The housing **1** (including the one or more pumps and a battery) and the container **3** are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container **3** is attached to a lower face **1**A of the housing **1** and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump **100** may be arranged to be used with just the right or the left breast specifically, the breast pump **100** is preferably used with both breasts, without modification. To this end, the outer surfaces of the breast pump **100** are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing **1** and milk container **3**) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system **100** gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focused on minimising the number of components.

The breast pump system **100** is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by FIG. **1**, is at around 60 mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40 mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85 mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60 mm below the centre of the nipple tunnel when the milk container is full. Generalizing, the centre of gravity should be at least 2 mm below the centre of the nipple tunnel when the container is empty.

The breast pump **100** is further provided with a user interface **5**. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump **100**. Such functions might include turning the breast pump **100** on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface **5** might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing **1**.

In the particular embodiment of the Figures, the user interface **5** comprises power button **5**A for turning the pump on and off. The user interface **5** further comprises pump up button **5**B and pump down button **5**C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button **5**B could be physically larger than the pump down button **5**C. A play/pause button **5**D is provided for the user to interrupt the pumping process without turning the device off.

The user interface **5** further comprises a breast toggle button **5**E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a pair of LEDs, one to the left of the toggle button **5**E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button **5**E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button **5**E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in FIG. **1**, the housing **1** and milk collection container **3** form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump **100** to substantially fit within the cup of a user's bra. The milk collection container **3** is retained in attachment with the housing **1** by means of a latch system, which is released by a one-click release mechanism such as a push button **2** or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container **3** has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump **100** of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost point of the breast pump **100**, and the second of which is aligned with the outermost point of the breast pump **100**. This distance is preferably less than 100 mm.

FIG. **2** is a rear view of the breast pump **100** of FIG. **1**. The inner surface of the housing **1** and milk collection container **3** are shown, along with a breast shield **7**. The housing **1**,

milk collection container **3** and breast shield **7** form the three major subcomponents of the breast pump system **100**. In use, these sub-components clip together to provide the functioning breast pump system **100**. The breast shield **7** is designed to engage with the user's breast, and comprises a concave inner flange **7**A which contacts the breast. To allow the breast pump **100** to be used on either of the user's breasts, the breast shield **7** is preferably substantially symmetrical on its inner flange **7**A.

The inner flange **7**A is substantially oval-shaped. While the inner flange **7**A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange **7**A and the outermost point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange **7**A of the breast shield **7** may extend over the majority of the inner surface of the housing **1** and milk collection container **3**. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield **7** substantially aligns with the outer edge **1**B of the housing **1**. The milk collection container **3** may be provided with an arcuate groove for receiving a lower part of the breast shield **7**. This is best shown in later Figures. In the assembled arrangement of FIGS. **1** and **2**, the inner surface of the breast pump **100** is substantially continuous.

The breast shield **7** comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel **9**) aligned with the opening and extending away from the user's breast. Breast shield nipple tunnel **9** extends from a curved section **7**B in the breast shield **7**. In preferable embodiments the nipple tunnel **9** is integral with the breast shield **7**. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section **7**B is positioned over the user's nipple and areola in use. The breast shield **7** forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel **9** defines a milk-flow path from the inner surface of the breast shield **7**A, through the breast shield nipple tunnel **9** and into the milk collection container **3**. The breast shield nipple tunnel **9** is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel **9** may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel **9** is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening **9**A for depositing milk into the collection container and a second opening **19**A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange **7**A and nipple tunnel **9** may be detachable from the housing **1** together. The shield flange **7**A and nipple tunnel **9** being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel **9** will be integral with the breast shield **7**, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

FIGS. **3** and **4** are of a partially disassembled breast pump **100** of the present invention. In these Figures, the breast shield **7** has been disengaged from the housing **1** and milk collection bottle **3**. As shown in FIG. **4**, the housing **1** comprises a region or slot **11** for receiving the breast shield nipple tunnel **9** of the breast shield **7**. The breast shield is held in place thanks to a pair of channels (**9**B) included in the nipple tunnel **9**, each channel including a small indent. When pushing the housing **1** onto the breast shield **7**, which has been placed over the breast, ridges in the housing (**9**C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each ridge facilitates movement of the housing on to the nipple tunnel **9**. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield **7** onto her breast and with her other hand, position and secure the housing **1** on to the breast shield **7**. The breast shield **7** can be readily separated from the housing **1** since the ball bearing latch only lightly secures the breast shield **7** to the housing **1**.

Alternatively, the breast shield **7** may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield **7**, with the slot in a corresponding location.

The breast shield nipple tunnel **9** of the breast shield **7** is provided with an opening **9**A on its lower surface through which expressed milk flows. This opening **9**A is configured to engage with the milk collection bottle **3**.

The breast pump **100** further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm **13** seated into diaphragm housing **19**A. The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing **19**A includes a small air hole into the nipple tunnel **9** to transfer negative air pressure into nipple tunnel **9** and hence to impose a sucking action on the nipple placed in the nipple tunnel **9**.

Hence, the air pump acts on one side of the barrier or diaphragm **13** to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing **19**A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing **19**A. The milk-flow path extending under the outer periphery or surface of the barrier **19**A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier **13** or surface of diaphragm housing **19**A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier **32**. This results in a simpler and smaller barrier design.

As noted, the diaphragm **13** is mounted on diaphragm housing **19**A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier **13** may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier **13**. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in FIGS. **3** and **4**, the barrier may include a flexible diaphragm **13** formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm **13** is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm **13**. This means that the milk-flow pathway does not extend through the diaphragm **13**. In particular, the milk-flow pathway is beneath the diaphragm **13**. However, the diaphragm **13** may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm **13**.

Preferably, the diaphragm **13** is a continuous membrane, devoid of any openings. The diaphragm **13** is held in a diaphragm housing **19**, which is formed in two parts. The first half **19**A of the diaphragm housing **19** is provided on the outer surface of the breast shield **7**, above the breast shield nipple tunnel **9** and hence the milk-flow pathway. In preferred embodiments, the first half **19**A of the diaphragm housing **19** is integral with the breast shield. The second half **19**B of the diaphragm housing is provided in a recessed portion of the housing **1**. The diaphragm **13** self-seals in this diaphragm housing **19** around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm **13** is the only seal of the diaphragm **13**. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm **13** mounted in the breast pump **100** in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield **7** and diaphragm **13** are the only components which need to be removed from the pump **100** for cleaning. Because the diaphragm **13** self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

FIGS. **5** and **6** show a breast pump **100** according to the present invention in a further disassembled state. In addition to the breast shield **7** and diaphragm **13** being removed, the milk collection container **3** has been unclipped. Preferably, the milk collection container **3** is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container **3** may be formed of three sections: a front bottle portion, a rear bottle portion, and a cap. These three sections may clip together to form the milk collection container **3**. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout **35** or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve **37** (or 'sealing plate seal') is mounted onto the cap or spout **35** and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve **37** self-seals against opening **9**A in nipple tunnel **9**. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system **100** is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container **3** has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container **3** preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container **3** further preferably has a height, extending in the direction from the bottom of the container **3** in use to the cap or spout or sealing plate **35**, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap **35** may screw into the milk collection bottle **3**. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container **3** in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap **35** is provided with a one-way valve **37**, through which milk can flow only into the bottle. This valve **37** prevents milk from spilling from the bottle once it has been collected. In addition, the valve **37** automatically seals completely unless engaged to the breast shield **7**. This ensures that when the pump **100** is dismantled immediately after pumping, no milk is lost from the collection bottle **3**. It can be appreciated that this one-way valve **37** might also be placed on the breast shield **7** rather than in this bottle cap **35**.

Alternatively, the milk bottle **3** may form a single integral part with a cap **35**. Cap **35** may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion **31**A or attach to the spout that is integral with cap **35**, to allow the container **3** to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion **31**A for ease of pouring. A cap may also be provided to attach to the protrusion **31**A in order to seal the milk collection bottle **3** for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement mark-

ings (**3**A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

FIGS. **7** and **8** show front views of a breast pump system **100**. The outer-surface of the housing **1** has been drawn translucent to show the components inside. The control circuitry **71** for the breast pump **100** is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container **3**. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button **5**E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry **71** for charging the battery **81**. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port **6** is shown for charging the battery **81**. This port **6** may be located anywhere appropriate on the housing **1**.

FIG. **8** shows the location of the battery **81** and the pumps **83**A, **83**B mounted in series inside the housing **1**. While the depicted embodiment shows two pumps **83**A, **83**B it is appreciated that the present invention may have a single pump. Preferably, an air filter **86** is provided at the output to the pumps **83**A, **83**B. In preferable embodiments, the pumps **83**A, **83**B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing **19**B in the housing **1** is provided with a pneumatic connection spout. The pumps **83**A, **83**B are pneumatically connected with this connection spout.

Operation of the breast pump **100** will now be described. Once the breast pump **100** is activated and a pumping cycle is begun, the pumps **83**A, **83**B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm **13** mounted on the diaphragm housing **19**A. This side of the diaphragm **13** is denoted the pumping side **13**B of the diaphragm **13**.

The diaphragm **13** transmits this negative air pressure to its opposite side (denoted the milk-flow side **13**A). This negative pressure is transferred through a small opening in the diaphragm housing **19**A to the breast shield nipple tunnel **9** and the curved opening **7**B of the breast shield **7** that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel **9**, to the one way valve **37** that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve **37** opens and milk flows under gravity past the valve **37** and into milk container **3**. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump **100** is provided with two pumps, the following schematics will be described with a single pump **83**. It is understood that the single pump **83** could be replaced by two separate piezo air-pumps **83**A, **83**B as above.

FIG. **9** depicts a schematic of a further embodiment of a breast shield nipple tunnel **9** for a breast pump **100**. The breast shield nipple tunnel **9** is provided with an antechamber **91** and a separation chamber **93**. A protrusion **95** extends from the walls of the breast shield nipple tunnel **9** to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel **9**. In the separation chamber **93** there are two opening **97**, **99**. An air opening **97** is provided in an upper surface **93**A of the separation chamber **93**. This upper surface **93** is provided transverse to the direction of the breast shield nipple tunnel **9**. This opening **97** connects to the first side of the diaphragm housing **19**A and is the source of the negative pressure. This airflow opening **97** also provides a route for air to flow as shown with arrow **96**. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel **9** without such a pathway will work.

The other opening **99** is a milk opening **99**. The milk opening **99** is provided on a lower surface **93**B of the separation chamber **93** and connects in use to the container **3**. After flowing through the tortuous breast shield nipple tunnel **9** pathway, the milk is encouraged to flow through this opening **99** into the container **3**. This is further aided by the transverse nature of the upper surface **93**A. In this manner, expressed milk is kept away from the diaphragm **13**. As such, the breast pump **100** can be separated into a "air" side comprising the pump **83**, the connection spout **85** and the pumping side **13**B of the diaphragm **13** and a "milk-flow" side comprising the breast shield **7**, the milk collection container **3** and the milk-flow side **13**A of the diaphragm **13**. This ensures that all of the "milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump **83**, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm **13**, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

FIG. **10** shows a schematic of a basic pneumatic system **200** for a breast pump **100**. In the system **200** milk expressed into the breast shield **7** is directed through the breast shield nipple tunnel **9** through the torturous air-liquid labyrinth

interface **95**. The milk is directed through the non-return valve **37** to the collection container **3**. This side of the system forms the "milk-flow" side **201**.

The rest of the pneumatic system **200** forms the air side **202** and is separated from contact with milk. This is achieved by way of a flexible diaphragm **13** which forms a seal between the two sides of the system. The diaphragm **13** has a milk-flow side **13**A and an air side or pumping side **13**B.

The air side **202** of the system **200** is a closed system. This air side **202** may contain a pressure sensor **101** in pneumatic connection with the diaphragm **13** and the pump **83**. Preferably, the pump **83** is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump **83** has an output **83**A for generating pressure, and an exhaust to the atmosphere **83**B. In a first phase of the expression cycle, the pump **83** gradually applies negative pressure to half of the closed system **202** behind the diaphragm **13**. This causes the diaphragm **13** to extend away from the breast, and thus the diaphragm **13** conveys a decrease in pressure into the breast shield **7**. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system **95** and the one-way valve **37** to the collection bottle **3**.

While in the depicted embodiment the air exhaust **83**B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side **202** further comprises a two-way solenoid valve **103** connected to a filtered air inlet **105** and the pump **83**. Alternatively, the filter could be fitted on the pump line **83**A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system **202** through the valve **103** in a second phase of the expression cycle. In this embodiment, the air filter **105** is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve **103** is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor **101**.

In certain embodiments, if the elasticity and extension of the diaphragm **13** may be approximated mathematically at different pressures, the pressure measured by sensor **101** can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm **13**. FIG. **11** shows an alternative pneumatic system **300**. The core architecture of this system is the same as the system shown in FIG. **10**.

In this system **300**, the closed loop **202** is restricted with an additional three way solenoid valve **111**. This valve **111** allows the diaphragm **13** to be selectively isolated from the rest of the closed loop **202**. This additional three way valve **111** is located between the diaphragm **13** and the pump **83**. The pressure sensor **101** is on the pump **83** side of the three way valve **111**. The three way valve **111** is a single pole double throw (SPDT) valve, wherein: the pole **111**A is in pneumatic connection with the pump **83** and pressure sensor; one of the throws **11** is in pneumatic connection with the diaphragm **13**; and the other throw **111**C is in pneumatic connection with a dead-end **113**. This dead-end **113** may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system **202**. This could include, for example, an arrangement of one-way valves.

In this system **300**, therefore, the pump **83** has the option of applying negative pressure directly to the pressure sensor **101**. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump **83** to the dead end **113**. The pump **83** then pulls directly against the dead end **113** and the reduction of pressure within the system can be detected by the pressure sensor **101**.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user-indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

FIG. **12** shows a schematic for a system **400** for a breast pump **100** which can estimate the volume of milk collected in the collection container **3** from data collected on the air-side part **202** of the system **400**.

The pump **83** is connected to the circuit via two bleed valves **126**, **128**. The first bleed valve **126** is arranged to function when the pump **83** applies a negative pressure. As such, this valve **126** is connected to a "bleed in" **127**, for supplying atmospheric air to the system **202**.

The second bleed valve **128** is arranged to function when the pump **83** applies a positive pressure. As such, this valve **128** is connected to a "bleed out" **129** for bleeding air in the system **202** to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump **83** applies negative pressure on the air side **13**B of the diaphragm **13** which causes its extension towards the pump **83**. This increases the volume of the space on the milk side **13**B of the diaphragm **13**. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves **121**, **123**, **125** ensure that this decrease in pressure is applied only to the breast (via the breast shield **7**) and not the milk collection container **3**. To measure the volume of milk collected in the container **3**, the pump **83** is used instead to apply positive pressure to the diaphragm **13**. The diaphragm **13** is forced to extend away from the pump **83** and conveys the pressure increase to the milk side **201** of the system **400**. The three non-return valves **121**, **123**, **125** ensure that this increase in pressure is exclusively conveyed to the milk collection container **13**.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm **13** from the air-side **202** by a pressure sensor **101**. Preferably, the pressure sensor **101** is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump **83** (at constant strength) is able to increase the pressure in the system **400** is a function of the volume of air that remains in the milk collection container **3**. As air is many times more compressible than liquid, the rate at which pressure increases in the system **400** can be expressed as an approximate function of the volume of milk held in the collection container **3**.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container **3** is calculable. FIG. **13** shows repeated milking and volume measurement cycles as the collection container **3** is filled. To determine the rate of pressure increase the pump **83** was run for a fixed time. As pumping proceeds and the volume of air reduces in the system **400**, the pump **83** is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike **41**. There is a clear upwards trend **43** in magnitude of positive pressures achieved as the collection container **3** is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container **3** based upon the measured pressures.

FIG. **13** also shows a dead end stop pump test **45** as described above. The negative spike shows the application of negative pressure directly to the pressure sensor **101**.

2. Breast Shield Sizing and Nipple Alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to FIG. **14**, three breast shield sizes are shown (A**1**, B**1**, C**1**). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A**2**, B**2**, C**2**). The transparent breast shield allows the user to observe the nipple while

adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct alignment is illustrated B**2**.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

FIGS. **15** to **20** show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

FIG. **15** shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

FIG. **16** shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

FIG. **17** shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (−) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

FIG. **18** shows a page providing a summary of the last recorded pumping session.

FIG. **19** shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. FIG. **20** shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

FIG. **21** shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre-program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in FIG. **22**.

FIG. **23** shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to FIG. **24**, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to FIG. **25**, a page summarizing the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast Pump Data Analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

FIG. **26** illustrates an outline of a smart breast pump system network which includes the breast pump system (**100**) in communication with a peripheral mobile device and application (**270**) and several cloud-based databases (**268**, **273**). The breast pump system (**100**) includes several sensors (**262**). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve(s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (**263**). In addition, any interactions, and data from these components, may be stored in memory (**264**).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (**265**) which can be used to communicate wirelessly with connected devices such as a peripheral mobile device (**270**). Through this connection any sensor data (**267**) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (**273**). In addition, the communication chip will also allow the sending of user control data/firmware updates from the connected device to the breast pump system (**266**).

Raw data (**271**) collected from the measurement sub-system including sensors (**262**) may be analysed on a cloud database and the analysed data may be stored on the cloud (**272**). Through inferences provided by the analysed data, firmware updates (**269**) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (**268**).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (**264**) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

the quantity of the liquid in the container above its base;

the height of the liquid in the container above its base;

the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

an estimation of the flow rate;

an estimation of the fill rate;

an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or tide angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

indicate whether the milk is flowing or not flowing,

measure or infer the quantity and/or height of the liquid in the container above its base,

give recommendations to the mother for optimal metrics for optimal milk flow,

give recommendations to the mother for optimal metrics for weaning,

give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),

give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,

automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.

automatically stop pumping when the milk container is full,

automatically adjust one or more pumping parameters to achieve an optimum pumping session,

automatically adjust one or more pumping parameters to achieve a comfortable pumping session,

automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically

adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymized and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

Section B: IR System

This section describes the milk detecting system used in the Elvie™ pump.

With reference to FIGS. **27** and **28**, there is shown a device **270** for use in detecting the level of liquid inside a container **275**. The device **270** is formed of a housing **271** in which is located a sensing assembly **272** comprising a series of optical emitters **273** (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver **274**. In operation of the device as will be described, each optical emitter **273** is operable to emit radiation which is received by the optical receiver **274**. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver **274**.

The optical emitters **273** and the optical receiver **274** from the sensing assembly **272** are located in a portion **276** of the device **270** which faces the container **275** when the device is connected to the container **275**. The portion **276** of the device **270** containing the optical emitters **273** and the optical receiver **274** comprises a window **277** of material which is transparent to optical radiation. In this way, each of the optical emitters **273** and the optical receiver **274** have a line of sight through the window **277** into the container **275** when the device **270** is connected thereto.

A controller **278** comprising a CPU **279** and a memory **280** is provided in the device **270** for controlling the operation of the sensing assembly **272**. An accelerometer **281** is also provided in the housing **271**, which is operatively connected to the controller **278**. Operation of the device **270** when connected to the container **275** will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container **275**, the controller **278** instructs the optical emitters **273** to each emit radiation towards the surface of the liquid inside the container **275** at a given intensity. The optical receiver **274** receives the reflected radiation from each optical emitter **273** via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly **272**, the controller **278** records the intensities of radiation emitted by each of the optical emitters **273** as intensities IE**1**; IE**2** . . . IEn (where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver **274** from each of the optical emitters **273** as received intensities IR1; IR2 . . . IRn.

By comparing the emitted radiation intensities IE**1**; IE**2** . . . IEn with the received radiation intensities IR**1**; IR**2** . . . IRn, the controller **278** calculates a series of intensity ratios IE**1**:IR**1**; IE**2**:IR**2** . . . IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE**1**:IR**1** is the same as IE**2**:IR**2**, given the optical emitters **273** are equidistant from the optical receiver **274**, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in FIG. **27**. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in FIG. **28**.

To accurately determine the level and the quantity of liquid inside the container **275**, the controller **278** processes the recorded intensity ratios using a database located in the memory **280**. The database contains an individual record for each container which is operable to connect with the device **270**. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE**1**:IR**1** and IE**2**:IR**2**) for the container **275** when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller **278** calculates the level and quantity of liquid inside the container **275** and stores this information in the memory **280**.

In situations where a container **275** to the device **270** contains no stored record in the database, the sensing assembly **272** can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly **272** is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller **278** calculates the recorded intensity ratios (IE**1**:IR**1** and IE**2**:IR**2**) and stores them in the record relating to the container **275**. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container **275**.

To improve the accuracy of the results obtained by the device **270** during its use, the controller **278** when recording each intensity ratio also records a parameter from the accelerometer **281** relating to the acceleration experienced by the device **270**. For each recorded acceleration parameter, the controller **278** determines whether the parameter **278** exceeds a predetermined threshold acceleration parameter stored in the memory **280**. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container **275** connected to the device **270**. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller **278** flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer **281**, the controller **278** is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller **278** checks

whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller **278** determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in FIG. **29**. In this event, the controller **278** flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters **273** with the radiation received by the optical emitter **274**, the controller **278** could instead record the time taken for radiation emitted by each of the optical emitters **273** to be received by the optical receiver **274**. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device **270**, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device **270** to determine the level of liquid located within a container **275**, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device **270** is associated with a breast pump **301** which assists with the expression of milk from a breast. The breast pump may be located in the housing **271** of the device **270** as shown in FIG. **30**, or it may be realizably connected to the housing **271**.

Either way, the device **270** would be connectable to the container **275** such that milk expressed by the breast pump can pass from the pump via a channel **302** into the container **275**.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible—further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10 nm and 1 mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device **270** is as a collar for detecting the level/quantity of liquid in a container **275**, such as a baby bottle, via its lid **310**. An example of the device **270** being used as such a collar is shown in FIG. **31**. In this arrangement, the device **270** is located between the container **275** and the lid **310**, and comprises a first end **311** having a first coupling **312** for attaching the collar to the lid **310**. The device comprises a second end **313** having a second coupling **314** for attaching the device **270** to the container **275**. The second coupling may be a screw thread, shown in FIG. **31**, on the inside surface of the container **275**. In this way, the distinctive bottom inside surface can be used by the sensing assembly **272** to more easily calibrate itself to the container **275** on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container **275** the device is connected to, and thus which record should be used from the database when the device **270** is used.

To further improve the accuracy of the sensing assembly **272**, the controller **278** may also be configured to use the recorded information from the accelerometer **281**, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller **278** may poll the accelerometer **281** prior to each operation of the sensing assembly **272** to verify that the device **270** is not currently undergoing excessive acceleration. In the event of the controller **278** determining excessive acceleration in the device **270**, the controller **278** would continually re-poll the accelerometer, and not operate the sensing assembly **272**, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory **280**.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity

ratios. In this way, the device **270** can more accurately determine the level/quantity of different liquids used in a particular container **275**.

As described herein, the sensing assembly **272** has been described as having a plurality of optical emitters **273**. It will be appreciated however that the sensing assembly could operate using a single optical emitter **273** and plurality of optical receivers **274**. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter **273** as received by each of the optical receivers **274**. In use of the device **270**, the controller **278** would then similarly record the emitted radiation from the optical emitter **273** as received by each of the optical receivers **274**. In an alternate arrangement, there may be provided a plurality of optical emitters **273** and a plurality of optical receivers **274**, wherein each optical emitter **273** is associated with a respective optical receiver **274**. In its simplest arrangement, the sensing assembly **272** may comprise a single optical emitter **273** and a single optical receiver **274**.

In certain configurations, the optical emitters **273** may together emit radiation having the same wavelength. In other configurations, the optical emitters **273** may each emit radiation having a different wavelength. In this latter configuration, the optical receiver **274** would then be able to determine which optical emitter **273** is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters **273** may also each emit radiation at different times, such to allow the controller **278** to more easily process the signals from the optical receiver **274**, and more easily distinguish between the radiation emitted by each of the optical emitters **273**.

In relation to the electrical connection between the controller **278** and the sensing assembly **272**, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device **270** herein described is preferably powered by a battery or some other power source located in the device **270**. In other embodiments, the device **270** may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller **278** comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container **275**, the controller **278** could instead process the recorded intensity ratios through a liquid-level equation stored in the memory **280**. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device **270**, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400 nm-700 nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700 nm-1 mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10 nm to 400 nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

Section C: Bra Clip

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in FIG. **32**, a typical maternity bra **320** comprises a support structure made up of shoulder straps **321** which support the bra **320** on the wearer's shoulders, and a bra band **322** for extending around a user's ribcage, comprising two wings **323** and a central panel or bridge **324**. The straps **321** are typically provided with adjustment mechanisms **325** for varying the length of the straps **321** to fit the bra **320** to the wearer. At the outermost end of each wing, an attachment region **326** is provided. Typically, hooks **327** and loops **328** are provided for securing the bra **320** at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region **326** may be provided at the front of the bra **320** in the bridge region **324**, with a continuous wing **323** extending continuously around the wearer's back. Typically, a number of sets of loops **328** are provided to allow for variation in the tightness of the bra **320** on the wearer. While shown as having a separation in FIG. **32**, the wings **323** and bridge **324** may form a single continuous piece in certain designs. Likewise,

while shown with a distinct separation in FIG. **32**, the shoulder straps **321** and the wings **323** may likewise form a single continuous piece.

The maternity bra **320** is further provided with two breast-supporting cups **329** attached to the support structure. The cups **329** define a cup size, which defines the difference in protrusion of the cups **329** from the band **322**. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups **329** from the band **322**. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc.

The cups **329** may be stitched to the bra band **321**. At least one of the cups **329**, is in detachable attachment with the corresponding strap **321**. In particular, this is achieved at attachment point **330** where a hook **331** attached to the bra strap **321** engages with a clasp **331** attached to the cup **329**. The hook **331** and the bra strap adjuster **325** are set such that in the closed position, the cup size of the bra **320** fits the wearer's breasts.

In FIG. **32**, the left cup **329** is shown attached to its attachment point **330**, which the right cup **329** is unattached. In this manner, the wearer is able to detach the cup **329** to expose their breast for feeding or for breast pumping. Once this is completed, the cup **329** is reattached and the maternity bra **320** continues to function as a normal bra.

While in the depicted embodiments, a hook **331** is shown on the bra strap **321** and a clasp **332** is shown on the cup **329**, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point **330** may be provided at a different location, such as at the attachment between the bra band **322** and the cup **329**. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

FIG. **33** depict a clip **335** according to the present invention, along with a clasp **332** shown in isolation from the bra cup **329** it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip **335** is provided with a material pathway **336** which receives a portion of the bra strap **321**. In the particular embodiment of these Figures, the clip **335** is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip **335** is designed to be attached to the bra strap **321** in a releasable manner, with the slot **336** acting as a support engaging mechanism. The releasable manner means that the clip **335** may be simply removed from the bra **320** without causing any damage to the functioning of the bra **320**. To enhance the ease of attachment, the clip **335** may be provided with outwardly extending wings **204** which help direct the bra strap **321** into the clip **335**. The clip **335** is further provided with a hook **220** acting as a cup engaging mechanism which can engage with the clasp **332**.

FIG. **33** (*c*) shows the clip **335** being attached to a bra strap **321** in order to provide a second attachment point **337** for the clasp **332** to attach to, and hence to provide a second cup size for the bra **320**. In this particular embodiment, the clip **335** is attached in a portion of strap **321**A below the original attachment point **330** and hence the second attachment point **337** is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip **335** engages with the support structure in a direction transverse to the direction in which it engages with the cup.

FIGS. **33** (*d*) and (*e*) show how a wearer is able to move between the first and second cup sizes. In **33**(*d*), the cup **329** is attached at the first attachment point **330** to provide a first cup size. The wearer then disengages the clasp **332** from the hook **331** at the hook **338** at the second engagement point **239**. In this manner, the wearer is easily able to transition between the two cup sizes.

FIGS. **34** and **35** show an alternative design for a clip **340**. This clip **340** is substantially "E-shaped", with a back portion **341** and first, second and 5 third prongs **342**A, **342**B, **342**C extending transverse from this back portion **341**. The three prongs **342**A, **342**B, **342**C are spaced apart along the length of the back portion **341**. The first and third prongs **342**A, **342**C are provided with attachment clips **343**A, **343**B.

These attachment clips **343**A, **343**B can engage with the clasp **332** of a bra to provide the second cup size. Depending upon the orientation of the clip **300**, one or the other of the attachment clips **343**A, **343**B will be used to attach the clasp **332** of the bra. By providing these clips **343**A, **343**B on both of the first and the third prongs **342**A, **342**C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip **340** is also symmetrical, to aid the reversibility of the clip **340**.

FIG. **35** shows the clip **340** attached to a bra. As can be seen, the first and third prongs **342**A, **342**C extend on the front side of the bra strap, with the second prong **342**B extending on the rear side of the bra strap. In this manner, the clip **340** is attached to the strap. In preferable embodiments, a grip-enhancing member **344** such as a number of projections and/or roughened patches can be provided on the second prong **342**B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centermost prong **342**B. In such an

arrangement, the centermost prong **342**B would be on the outside of the bra, with the first and third prongs **342**A, **342**C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point **330** when the breast pump device is not being used. As shown in FIG. **33**, the clasp **332** is then engaged by the user to discretely switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip **360** as shown in FIG. **36**. In such an embodiment the clip is attached to the hook **331** on the strap **321** in a releasable manner, with the clasp **332** attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp **332** is held in substantially the same position as the first attachment point **330** to provide the first cup size, and an expanded state, where the clasp **332** is held in a second position away from the first attachment point **330** to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook **331** is provided at the first end, and a second attachment point for attaching to the clasp **332** is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp **332** is held in substantially the same location as the first attachment point **330** to provide the first cup size, and in the open position the clasp is held away from the first attachment point **330** to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in FIGS. **37** and **38**. The alternative proposed solution is a small adapter device, which comprises a first portion **370** including a clasp **373** and a second portion **372** including a hook **374**, in which the first and second portions are separated by a small distance **371** in order to provide two different adjustable sizes. The first portion includes a clasp **373** that is designed to attach to the hook on the bra strap **321**. It may also include a top hook **375** positioned underneath the clasp, and a clip **376** on the rear side. The second portion includes a bottom hook **372**.

The clasp **332** that is present on the cup **329** of the maternity bra, may then either engage with the top hook (**321**) to provide a first cup size, and engage with the bottom hook (**332**) to provide a second cup size that is different from the first cup size, as illustrated in FIG. **39**. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (**100**).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter.

Each individual Piezo pump weighs approximately 6 gm and may, with material and design improvements, weigh less than 6 gm.

In operation, the Elvie breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise; tests indicate that it makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of FIGS. **7** and **8**, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to FIG. **40**, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to FIG. **41**, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to FIG. **42**, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In this example, the parallel configuration produces higher flow rate and achieves −100 mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100 mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at −140 mmHg. In comparison, the series configuration is able to generate about −240 mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

FIG. **43** shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500 ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48° C. and preferably no more than 43° C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

FIG. **44** shows a picture of a wearable breast pump housing including multiple piezo pumps (**440**). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore connected to a heat sink (**441**), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

Wound therapy;

High degree burns;

Sleep apnoea;

Deep vein thrombosis;

Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. Elvie Breast Pump: General Usability Feature Cluster

B. Elvie Piezo Air Pump Feature Cluster

C. Elvie Milk Container Feature Cluster

D. Elvie IR System Feature Cluster

E. Elvie Bra Clip Feature Cluster

F. Other Features, outside the breast pump context

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1-42 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is Wearable and Includes Only Two Parts that are Removable from the Pump Main Housing in Normal Use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.

Milk only flows through the breast shield and then directly into the milk container.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

No other parts are removable from the breast shield, apart from the flexible diaphragm.

The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

The milk container mechanically or magnetically latches to the housing.

The milk container is released by the user pressing a button on the housing.

The milk container includes a removable cap and a removable valve that is seated on the lid.

In normal use, the milk container is positioned entirely within a bra.

No other parts are removable from the milk container, apart from the cap and the valve.

All parts that are user-removable in normal use are attached to either the breast shield or the milk container.

Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is Wearable and Includes a Clear Breast Shield Giving an Unobstructed View of the Breast for Easy Nipple Alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.

The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.

Entire breast shield is substantially transparent.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

The milk container mechanically or magnetically latches to the housing.

The milk container is released by the user pressing a button on the housing.

The milk container includes a removable cap and a removable valve that is seated on the lid.

In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is Wearable and Includes a Clear Breast Shield with Nipple Guides for Easy Breast Shield Sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.

Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is Wearable and Includes a Breast Shield that Audibly Attaches to the Housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is Wearable and Includes a Breast Shield that Attaches to the Housing with a Single Push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

The single push action overcomes a latching resistance.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

The milk container mechanically or magnetically latches to the housing.

The milk container is released by the user pressing a button on the housing.

The milk container includes a removable cap and a removable valve that is seated on the lid.

In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is Wearable and not Top Heavy, to Ensure Comfort and Reliable Suction Against the Breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.

In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.

System is configured so that its centre of gravity is no more than 60 mm up from the base of the milk container also below the top of the user's bra cup.

In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.

In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is Wearable and has a Night Mode for Convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Control system is implemented in hardware in the pump itself using a 'night mode' button.

Control system is implemented in software within a connected device app running on the user's smartphone.

Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is Wearable and Includes a Haptic or Visual Indicator Showing when Milk is Flowing or not Flowing Well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase

The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The haptic and/or visual indicator provides an indication of an estimation of the flow rate.

The visual indicator provides a colour-coded indication of an estimation of the flow rate.

The visual indicator provides an indication of how much of the container has been filled.

The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.

The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.

A sub-system measures or infers the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.

A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.

Milk container is attached to the lower part of the housing and forms the base of the breast pump system.

Milk container is made of transparent material.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 Elvie is Wearable and Collects Data to Enable the Mother to Understand What Variables (e.g. Time of Day, Pump Speed Etc.) Correlate to Good Milk-Flow

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

User-defined requirement is to enhance or increase milk-flow.

User-defined requirement is to reduce milk-flow.

The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.

The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.

measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.

Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Data analysis system gives recommended metrics for improving milk flow

Data analysis system gives recommended metrics for weaning.

Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).

Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.

Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.

Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).

The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.

The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is Wearable and Collects Data that can be Exported to Social Media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.

The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.

The social media or community function or platform organizes the collected data into different profiles.

The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.

each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.

Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

The application is connected to other applications residing on the connected device, such as a fitness app.

The collected data includes data received from other connected apps.

The collected data is anonymized before it is shared.

The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.

The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is Wearable and has a Smart Bottle that Stores the Time and/or Date of Pumping to Ensure the Milk is Used when Fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Memory or tag is programmed to store the quantity of milk in the milk container.

Memory or tag stores the milk expiry date.

Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.

System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.

Clock is in the housing.

Clock is in the milk container.

Milk container includes a display that shows the time and/or date it was filled with milk.

Milk container includes a display that shows the quantity of milk that it was last filled with milk.

Milk container includes a display that shows whether the left or right breast was used to fill the milk container.

Memory or tag is connected to a data communications sub-system.

Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.

Reader device shows the time and/or date a specific milk container was filled with milk.

Reader device shows the quantity of milk that a specific milk container was last filled with.

Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.

Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.

A sub-system measures or infers milk flow into the milk container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is

sufficiently still to permit the sub-system to accurately measure or infer the quantity and/Tr the height of the liquid in the container.

The sub-system is in the housing.

Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 a Smart Bottle that Stores the Time and/or Date of Pumping to Ensure the Milk is Used when Fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

The container includes wireless connectivity and connects to a companion app.

The memory or tag includes an NFC chip and is read using a NFC reader.

The memory or tag stores also an expiry date.

Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.

The memory or tag stores also the quantity of milk stored.

System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.

Clock is in the housing.

Clock is in the container.

Milk container includes a display that shows the time and/or date it was filled with milk.

Milk container includes a display that shows the quantity of milk that it was last filled with milk.

Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.

Milk container includes a display that shows the expiry date.

memory or tag is connected to a data communications sub-system.

Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.

Reader device shows the time and/or date a specific milk container was filled with milk.

Reader device shows the quantity of milk that a specific milk container was last filled with.

Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.

Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.

Reader device shows the expiry date.

Container includes wireless connectivity and connects to a companion application.

An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.

The pump is wearable.

The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.

Container is used for liquids other than milk.

Feature 13 Elvie is Wearable and Includes a Sensor to Infer the Amount of Movement or Tilt Angle During Normal Use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.

If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.

When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.

If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.

The container includes an optically clear region.

There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.

The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.

If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.

The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.

The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.

System includes a breast shield that attaches to the housing.

System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie Includes a Control to Toggle Between Recording Whether Milk is being Expressed from the Left Breast and the Right Breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

Control interface is a physical interface on the housing.

Control interface is a single button on the housing.

Control interface is from an application running on a device, such as a smartphone or smart ring.

Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.

The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.

The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.

Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie Includes a Pressure Sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements

The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.

The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.

The air pressure sensor detects pressure created by the pumping mechanism.

Sensor is a piezo air pressure sensor

Air pressure sensor measures the negative air pressure during a normal milk expression session.

Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.

Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance

Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.

The operation of the pumping mechanism is varied by altering the duty or pump cycle.

The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie Includes a Microcontroller to Enable Fine Tuning Between Pre-Set Pressure Profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

The user manually varies the pressure using a control interface on a housing of the breast pump system

The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.

The user manually varies the pressure by altering a control parameter of the pumping mechanism.

The user manually varies the pressure by altering the duty cycle or timing of the pumping mechanism.

The user manually varies the pressure by altering the voltage applied to the pumping mechanism.

The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Pressure profile defines one or more maximum negative air pressure levels.

Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.

Pressure profile defines one or more cycle time.

Pressure profile defines peak flow rate.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie Enables a User to Set the Comfort Level they are Experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system

The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.

The system stores user-indicated comfort levels together with associated parameters of the pumping system.

The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.

The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.

System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.

System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie Includes a Microcontroller to Dynamically and Automatically Alter Pump Operational Parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.

The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.

The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.

The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.

The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.

Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.

System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie Automatically Learns the Optimal Conditions for Let-Down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.

The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.

The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold or are otherwise acceptable to the user.

The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.

The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.

parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.

System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is Wearable and has a Piezo Air-Pump for Quiet Operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The closed system is separated from a 'milk' side by a flexible diaphragm.

Deformable diaphragm is removably mounted against a part of a breast shield.

Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.

Deformable diaphragm is not physically connected to the piezo air-pump.

Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield

Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

The piezo pump is fed by air that passes through an air filter.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a Piezo Air-Pump and Self-Sealing Diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The closed system is separated from a 'milk' side by the flexible diaphragm.

Deformable diaphragm is removably mounted against a part of a breast shield.

Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.

Deformable diaphragm is not physically connected to the piezo air-pump.

Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.

Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

The piezo pump is fed by air that passes through an air filter.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie Uses More than One Piezo Air Pump in Series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.

An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

Each piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

Each piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

Each piezo pump is fed by air that passes through an air filter.

Each piezo air pump forms part of a closed or closed loop system.

Each piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is Wearable and has a Piezo Air-Pump, a Breast Shield and a Diaphragm that Fits Directly onto the Breast Shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Piezo air pump is position at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum. power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise. The piezo pump is fed by air that passes through an air filter.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is Wearable and has a Piezo Air-Pump for Quiet Operation and a Re-Useable, Rigid Milk Container for Convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

Piezo air pump forms part of a closed or closed loop system.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The closed system is separated from a 'milk' side by a flexible diaphragm.

A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

The deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a Piezo-Pump for Quiet Operation and is a Connected Device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.

The data collection and transmission relates to any other operational data of the system.

Piezo air pump forms part of a closed or closed loop system.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

The closed system is separated from a 'milk' side by a flexible diaphragm.

A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.

The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie Uses a Piezo in Combination with a Heat Sink that Manages the Heat Produced by the Pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48° C. and preferably no more than 43° C.

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.

Heat sink warms a breast shield.

Piezo air pump forms part of a closed or closed loop system.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps, each connected to its own or a shared heat sink.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

The closed system is separated from a 'milk' side by a flexible diaphragm.

A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

The deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

Feature 27 Elvie is Wearable and Gently Massages a Mother's Breast Using Small Bladders Inflated by Air from its Negative Pressure Air-Pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

Air-pump is a piezo pump.

Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.

Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is Wearable and Gently Warms a Mother's Breast Using Small Chambers Inflated by Warm Air from its Negative Pressure Air-Pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.

The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is Wearable and Includes a Re-Useable, Rigid Milk Container that Forms the Lower Part of the Pump, to Fit Inside a Bra Comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is attached to the housing with a push action.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.

The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is Wearable and Includes a Milk Container that Latches to the Housing with a Simple Push to Latch Action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.

Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.

The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.

Mechanism that attaches or latches the milk container into position does so with an audible click.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is Wearable and Includes a Removable Milk Container with an Integral Milk Pouring Spout for Convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

Spout is integral to the milk container.

Spout is integral to a removable lid to the milk container.

Spout is positioned at or close to the front edge of the milk container.

Spout is removable from the container, such as by clipping off the container.

A teat is attachable to the spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is Wearable and Includes a Removable Milk Container Below the Milk Flow Path Defined by a Breast Shield for Fast and Reliable Milk Collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.

Milk flows from the opening directly into the milk container.

Milk flows from the opening directly into the milk container.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.

Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.

Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is Wearable and Includes a Breast Shield and Removable Milk Container of Optically Clear, Dishwasher Safe Plastic for Ease of Use and Cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

The material is a polycarbonate material, such as Tritan™.

breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is Wearable and Includes Various Components that Self-Seal Under Negative Air Pressure, for Convenience of Assembly and Disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.

The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.

The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.

The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is Wearable and Includes a Spout at the Front Edge of the Milk Container for Easy Pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.

Spout is integral to a removable lid to the milk container.

Spout is removable from the container, such as by clipping off the container.

A teat is attachable to the spout.

By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.

The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.

The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is Wearable and Includes a Milk Container that is Shaped with Broad Shoulders and that can be Adapted as a Drinking Bottle that Baby can Easily Hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

Teat is attachable directly to the milk container.

Pouring or drinking spout is integral to the milk container.

The shoulders are at least 2 cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.

Spout/teat/straw resides near the edge of the container's rim.

Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.

The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Spout is integral to the milk container.

Spout is integral to a removable lid to the milk container.

Spout is positioned at or close to the front edge of the milk container.

Spout is removable from the container, such as by clipping off the container.

A teat is attachable to the spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is Wearable and Includes a Light-Based System that Measures the Quantity of Milk in the Container for Fast and Reliable Feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;

(b) at least one light emitter, configured to direct radiation towards the surface of the milk;

(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.

Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.

Milk-flow data is captured and stored.

If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 the Separate IR Puck for Liquid Quantity Measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

The quantity of milk is measured as milk enters the container or as milk is removed from the container.

Measured property includes the reflected light intensity

Feature 39 the Separate IR Puck Combined with Liquid Tilt Angle Measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

Measured property includes the reflected light intensity

The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally Applicable Optional Features

Weight of the entire unit, unfilled, is under 250 g and preferably 214 g.

Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.

Housing includes a rechargeable battery.

System is self-contained.

System is a closed loop system.

Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.

Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.

Bra adjuster is extensible or elastic.

Bra adjuster is of a fixed length.

Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.

Bra adjuster is machine-washing washable.

F. Other Features that can Sit Outside the Breast Pump Context

Feature 41 Wearable Device Using More than One Piezo Pump Connected in Series or in Parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

The wearable device is a medical wearable device.

The piezo pumps air or any liquid etc.

The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable Medical Device Using a Piezo Pump and a Heat Sink Attached Together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

The wearable device uses more than one piezo pump connected in series.

The wearable device uses more than one piezo pump connected in parallel.

Each piezo pump is connected to its own heat sink, or to a common heat sink.

The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48° C. and preferably no more than 43° C.

The wearable device includes a thermal cut out.

Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.

Use cases application:

Wound therapy

High degree burns

Sleep apnea

Deep vein thrombosis

Sports injury.

Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

The invention claimed is:

1. A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:

a housing that includes:

a battery, and

a pump powered by the battery and generating negative air pressure;

a breast shield made up of a breast flange and a nipple tunnel;

a milk container that is configured to be attached to and removed from the housing; and

a diaphragm configured to be seated against a diaphragm holder that forms a recess or cavity at least in part with an external surface of the housing, the diaphragm deforming in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

2. The breast pump device of claim **1**, wherein the pump comprises a piezo air pump system.

3. The breast pump device of claim **1**, wherein the pump is positioned at or close to a base of the housing.

4. The breast pump device of claim **1**, wherein a total mass of the breast pump device, unfilled with milk, is less than 250 gm.

5. The breast pump device of claim **1**, wherein the breast pump device makes less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

6. The breast pump device of claim **1**, wherein the breast shield is substantially rigid.

7. The breast pump device of claim **1**, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

8. The breast pump device of claim **1**, wherein the breast shield is a one piece item that, in use, presents a single continuous surface to a nipple and a breast.

9. The breast pump device of claim **1**, wherein the breast shield integrates the breast flange and nipple tunnel as a one-piece item.

10. The breast pump device of claim **1**, wherein the breast flange and the nipple tunnel are a single, integral item with no joining stubs.

11. The breast pump device of claim **1**, wherein the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use.

12. The breast pump device of claim **1**, wherein the housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

13. The breast pump device of claim **1**, wherein the breast pump device includes only the breast shield and the milk container that are directly removable from the housing in normal use or normal dis-assembly.

14. The breast pump device of claim **1**, wherein the diaphragm is a flexible membrane.

15. The breast pump device of claim **1**, wherein the diaphragm is substantially circular and is configured to self-seal under the negative air pressure to a substantially circular diaphragm holder that is part of the housing.

16. The breast pump device of claim **1**, wherein the milk container is substantially rigid.

17. The breast pump device of claim **1**, wherein the milk container is configured to attach to a lower part of the housing and to form a flat bottomed base for the breast pump device.

18. The breast pump device of claim **1**, wherein the milk container has a surface shaped to continue a curved shape of the housing, so that the breast pump device can be held comfortably inside the bra.

19. The breast pump device of claim **1**, wherein the milk container includes a flexible valve that self-seals under negative air pressure against a milk opening in the nipple tunnel and that permits milk to flow into the milk container.

20. The breast pump device of claim **1**, wherein the milk container is attachable to the housing with a mechanical or magnetic mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

21. The breast pump device of claim **1**, wherein the milk container includes a cap that is removable from the milk container and a removable valve that enables milk to pass into the milk container in one direction.

22. The breast pump device of claim **1**, wherein a top of the milk container includes an optically clear region that is aligned below one or more light emitters positioned in a base of the housing.

23. The breast pump device of claim **1**, wherein the milk container is wider than the milk container is tall.

24. The breast pump device of claim **1**, wherein the housing includes a wireless data communications system powered by the battery.

25. The breast pump device of claim **1**, wherein the housing has a front surface that is configured to fit inside a bra and to contact an inner surface of the bra, and a rear surface that is shaped to contact, at least in part, the breast shield.

26. The breast pump device of claim **1**, wherein the housing includes at least one of a visual or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

27. The breast pump device of claim **1**, wherein the housing includes at least one of a visual or haptic indicator that indicates if the pump is operating correctly to pump milk, based on whether a quantity or a height of liquid in the milk container above a base of the milk container is increasing above a threshold rate of increase.

28. The breast pump device of claim **1**, wherein the battery is a rechargeable battery, and the housing further includes:

a power charging circuit for controlling the charging of the rechargeable battery, and

control electronics powered by the rechargeable battery.

* * * * *

Exhibit 24

US011413380B2

(12) **United States Patent**
O'Toole et al.

(10) **Patent No.: US 11,413,380 B2**
(45) **Date of Patent: Aug. 16, 2022**

(54) **BREAST PUMP SYSTEM**

(71) Applicant: **CHIARO TECHNOLOGY LIMITED**, London (GB)

(72) Inventors: **Jonathan O'Toole**, Bristol (GB); **Adam Rollo**, London (GB); **Andrew Carr**, Edinburgh (GB)

(73) Assignee: **Chiaro Technology Limited**, London (GB)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(65) **Prior Publication Data**

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(Continued)

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Jun. 15, 2017 (GB) 1709561
Jun. 15, 2017 (GB) 1709564
(Continued)

(51) **Int. Cl.**
A61M 1/06 (2006.01)
G16H 40/63 (2018.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 1/062*** (2014.02); ***A61M 1/06*** (2013.01); ***A61M 1/066*** (2014.02); ***G16H 40/63*** (2018.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 1/062; A61M 1/066; A61M 1/06; A61J 13/00; A41C 4/04
See application file for complete search history.

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Whisper Wear Hands-Free Breast Pump, Model: WWPMP01, User Guide, pp. 1-20, Distributed with product at least as early as 2007 (see https://web.archive.org/web/20070621162539/http://www.whisperwear.com/pump_single.html).
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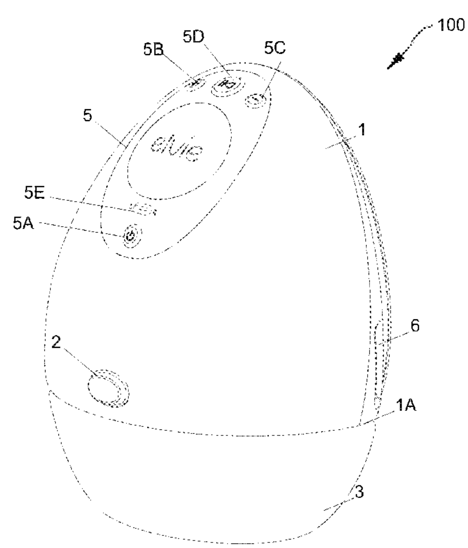
Primary Examiner — Nathan R Price
Assistant Examiner — Courtney B Fredrickson
(74) *Attorney, Agent, or Firm* — Sterne, Kessler, Goldstein & Fox P.L.L.C.

(57) **ABSTRACT**

The invention is a wearable breast pump system including a housing shaped at least in part to fit inside a bra and a piezo air-pump. The piezo air-pump is fitted in the housing and forms part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure. The diaphragm is removably mounted on a breast shield.

46 Claims, 44 Drawing Sheets



Related U.S. Application Data

No. 16/009,547, filed on Jun. 15, 2018, now Pat. No. 10,926,011.

(30) **Foreign Application Priority Data**

Jun. 15, 2017 (GB) 1709566
Jun. 1, 2018 (GB) 1809036

(51) **Int. Cl.**
A41C 3/04 (2006.01)
A61J 9/00 (2006.01)
A61M 39/22 (2006.01)
A61M 39/24 (2006.01)

(52) **U.S. Cl.**
CPC . *A41C 3/04* (2013.01); *A61J 9/00* (2013.01); *A61M 39/223* (2013.01); *A61M 39/24* (2013.01); *A61M 2205/07* (2013.01); *A61M 2205/10* (2013.01); *A61M 2205/3313* (2013.01); *A61M 2205/3327* (2013.01); *A61M 2205/3334* (2013.01); *A61M 2205/3344* (2013.01); *A61M 2205/3389* (2013.01); *A61M 2205/3553* (2013.01); *A61M 2205/3584* (2013.01); *A61M 2205/3606* (2013.01); *A61M 2205/502* (2013.01); *A61M 2205/505* (2013.01); *A61M 2205/52* (2013.01); *A61M 2205/581* (2013.01); *A61M 2205/582* (2013.01); *A61M 2205/583* (2013.01); *A61M 2205/584* (2013.01); *A61M 2205/587* (2013.01); *A61M 2205/6054* (2013.01); *A61M 2205/702* (2013.01); *A61M 2205/7536* (2013.01); *A61M 2205/80* (2013.01); *A61M 2205/8206* (2013.01); *A61M 2209/082* (2013.01); *A61M 2209/088* (2013.01)

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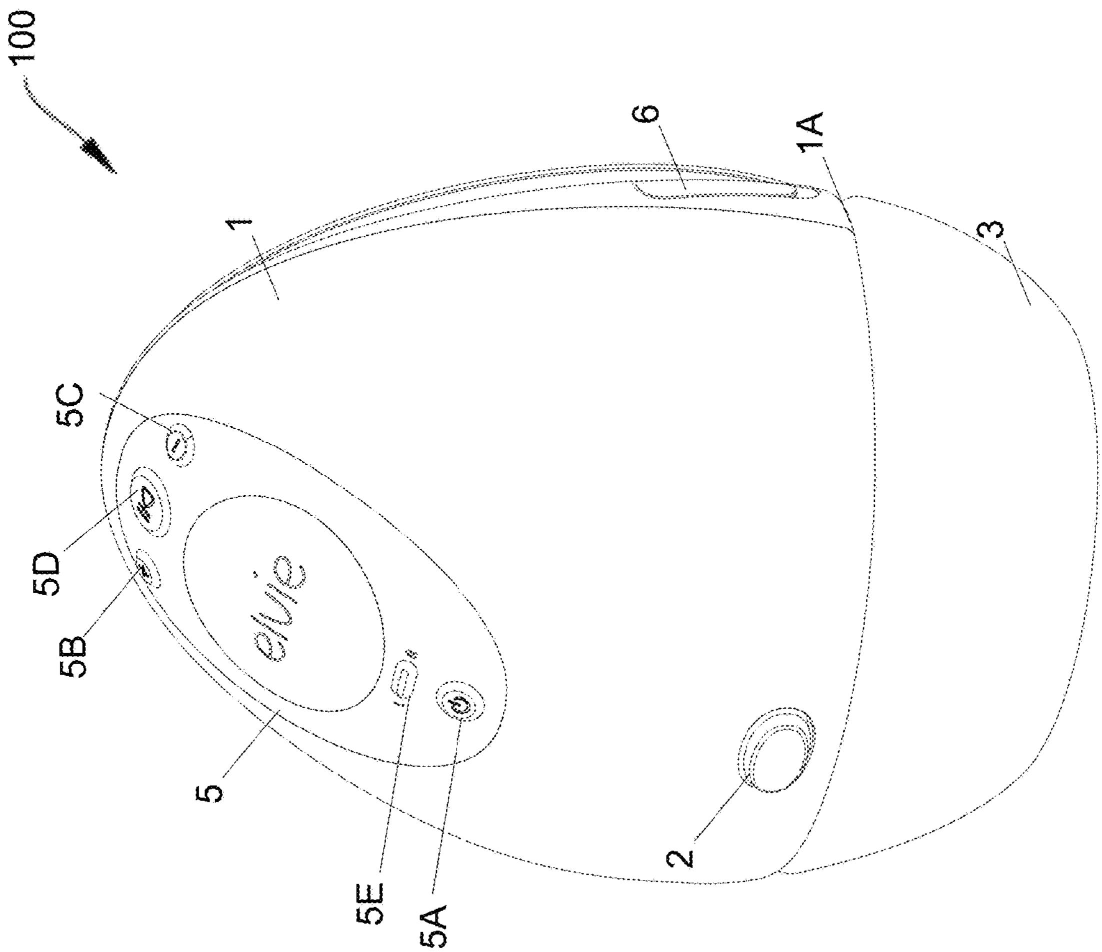

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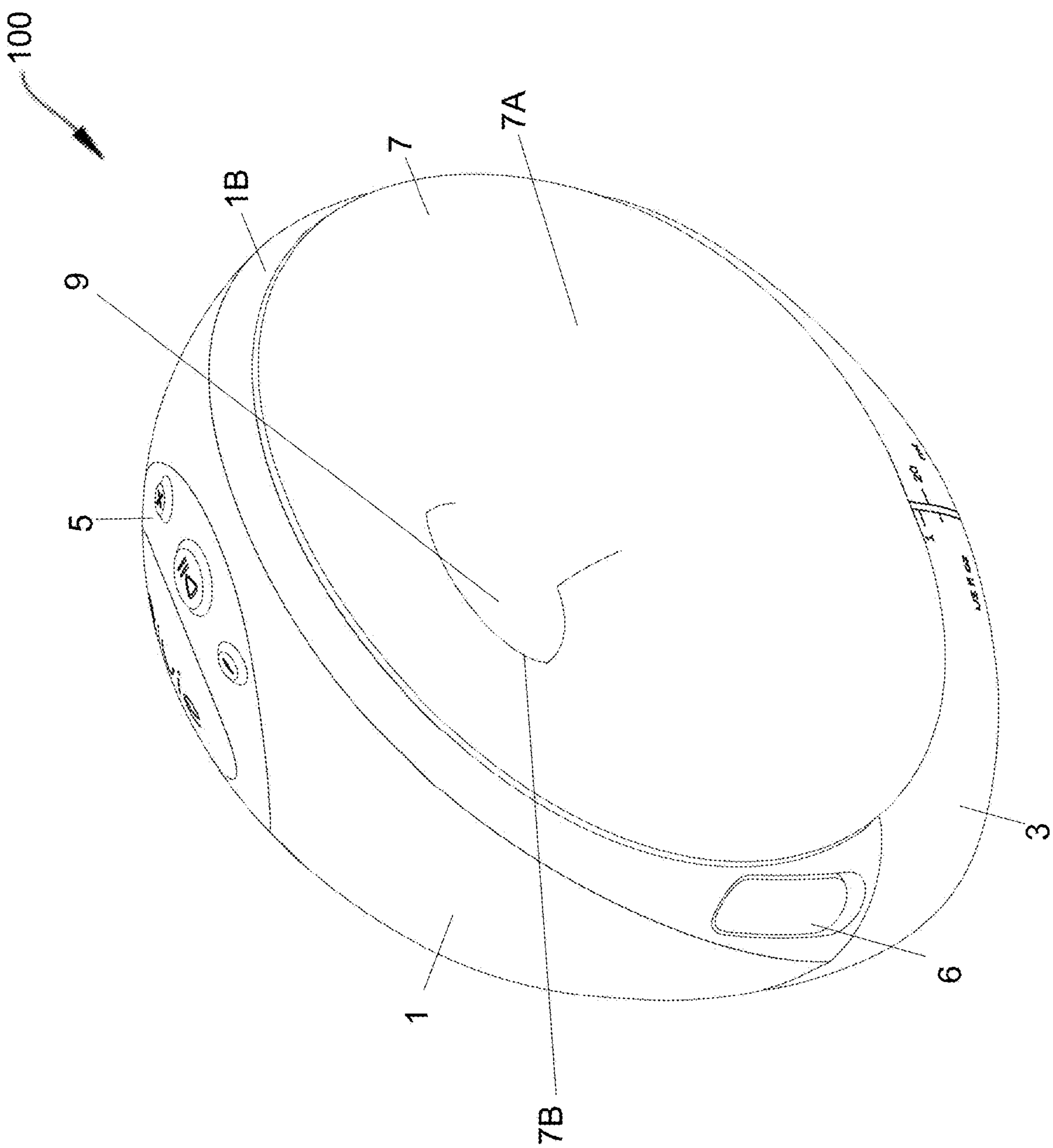

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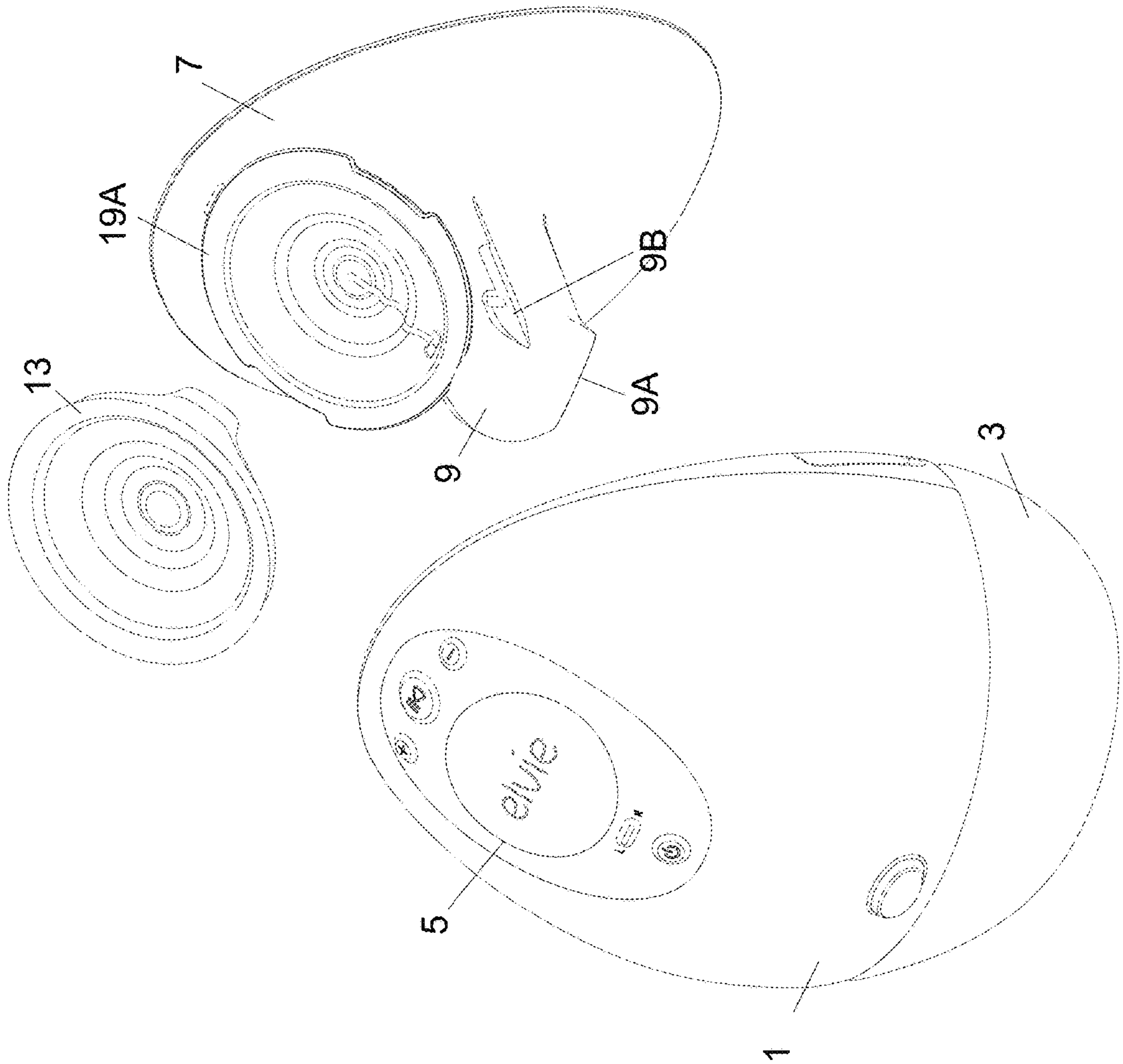

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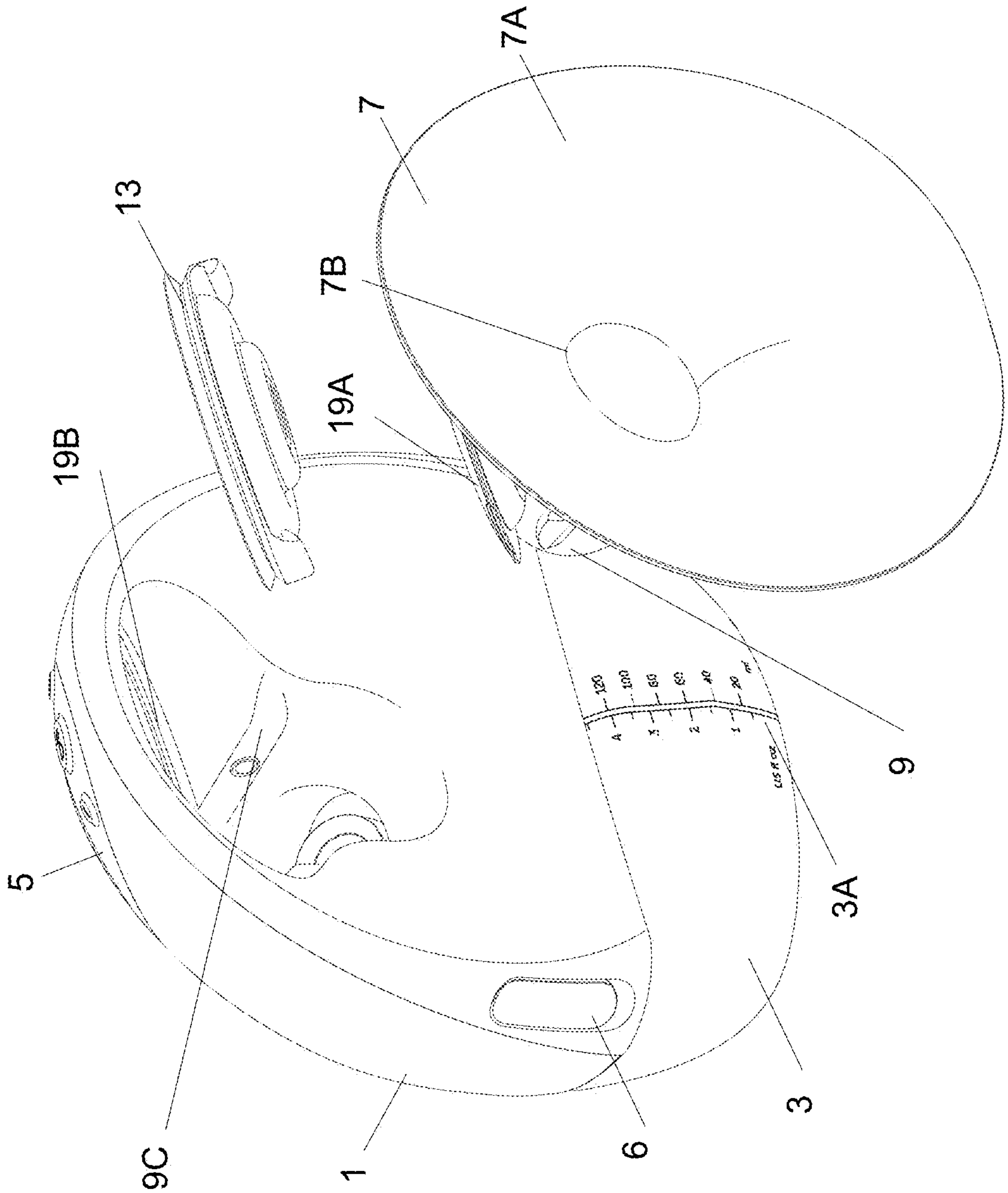

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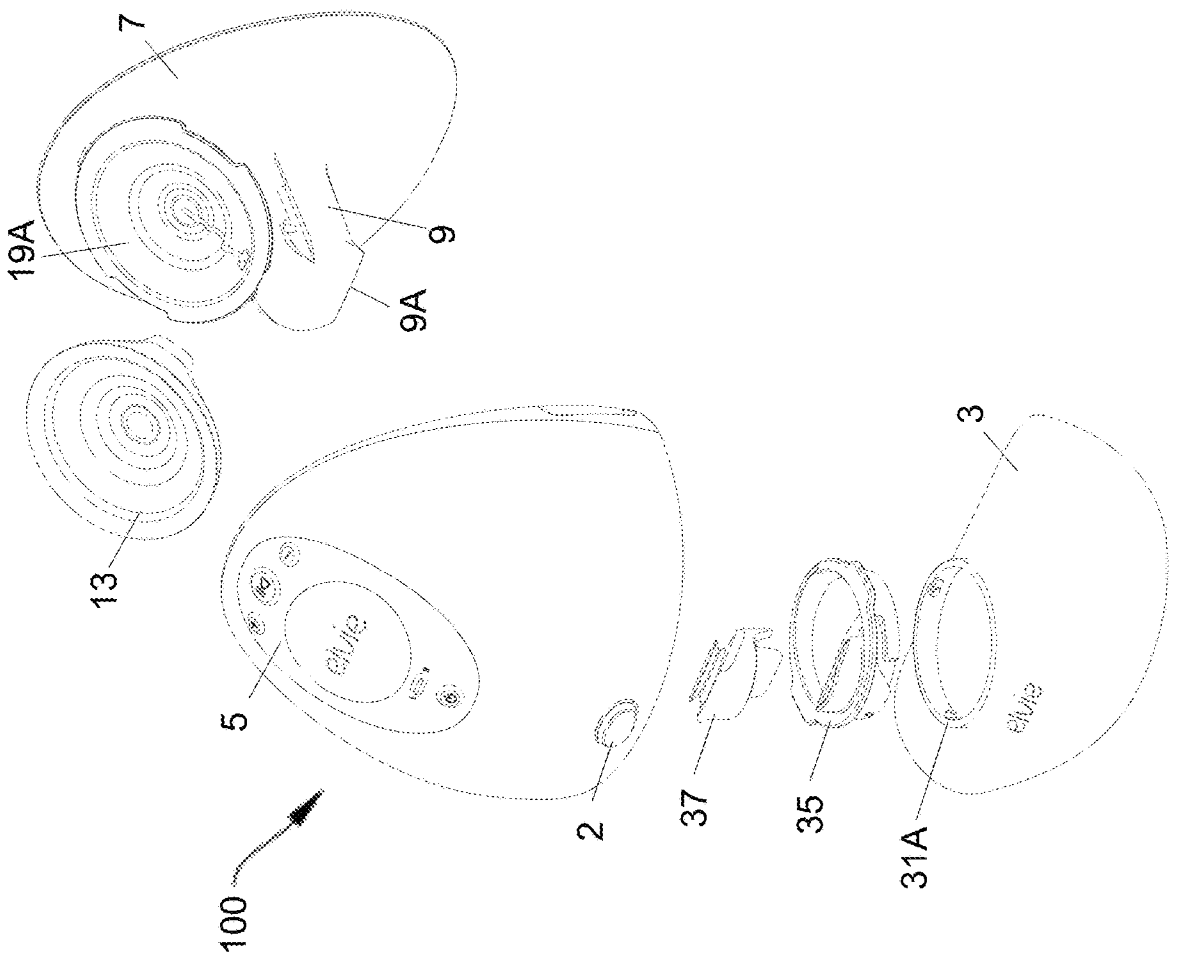

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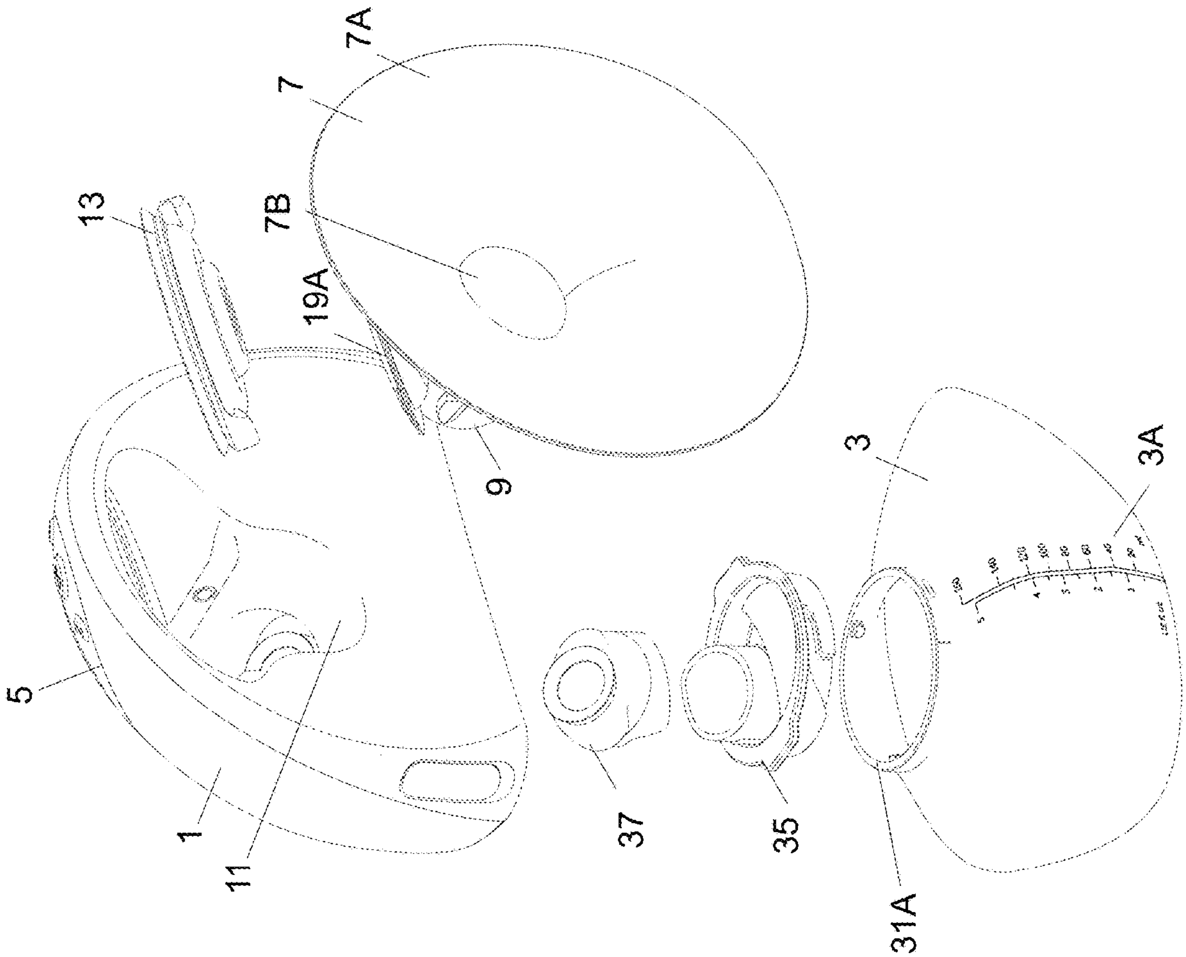

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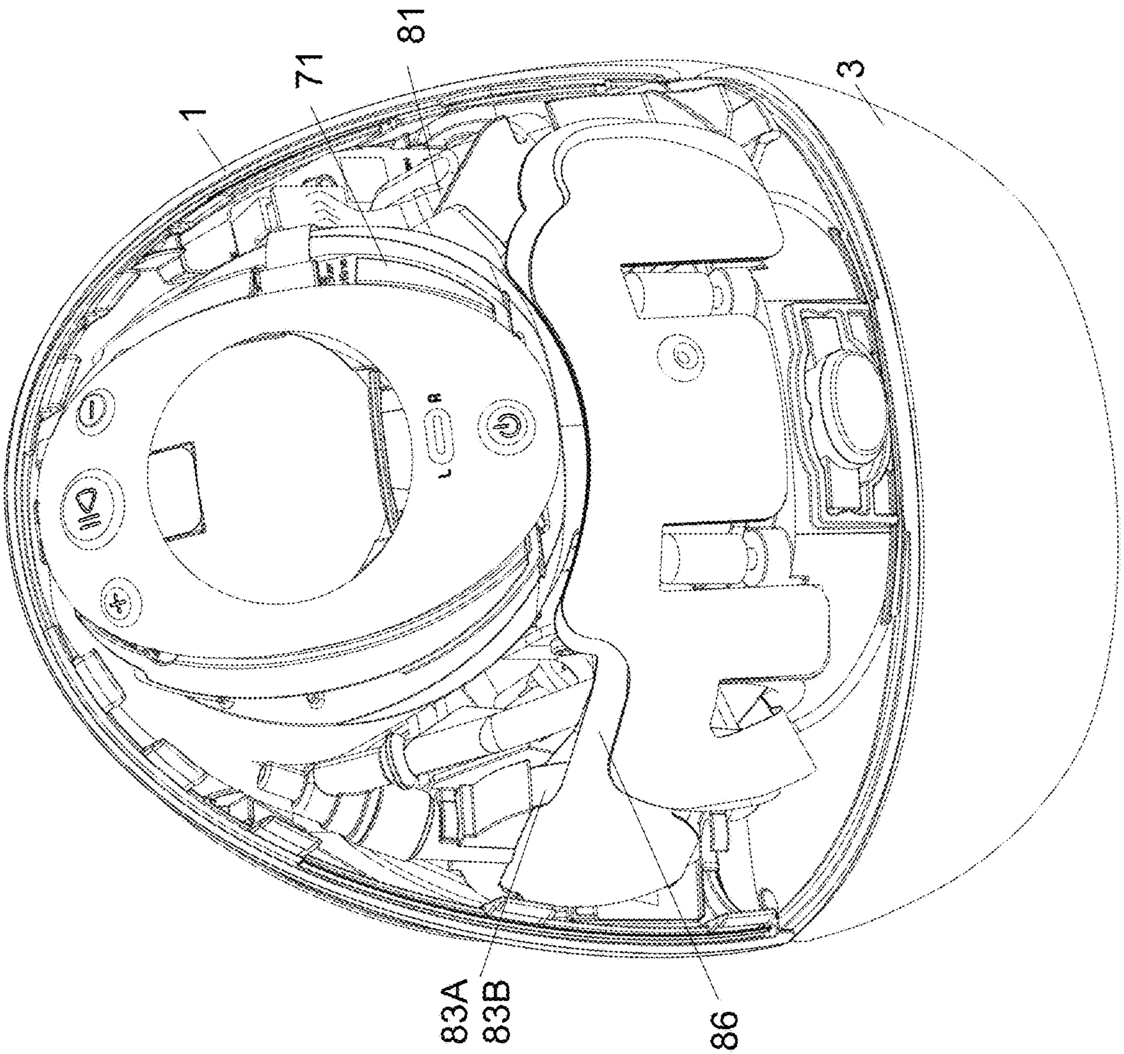

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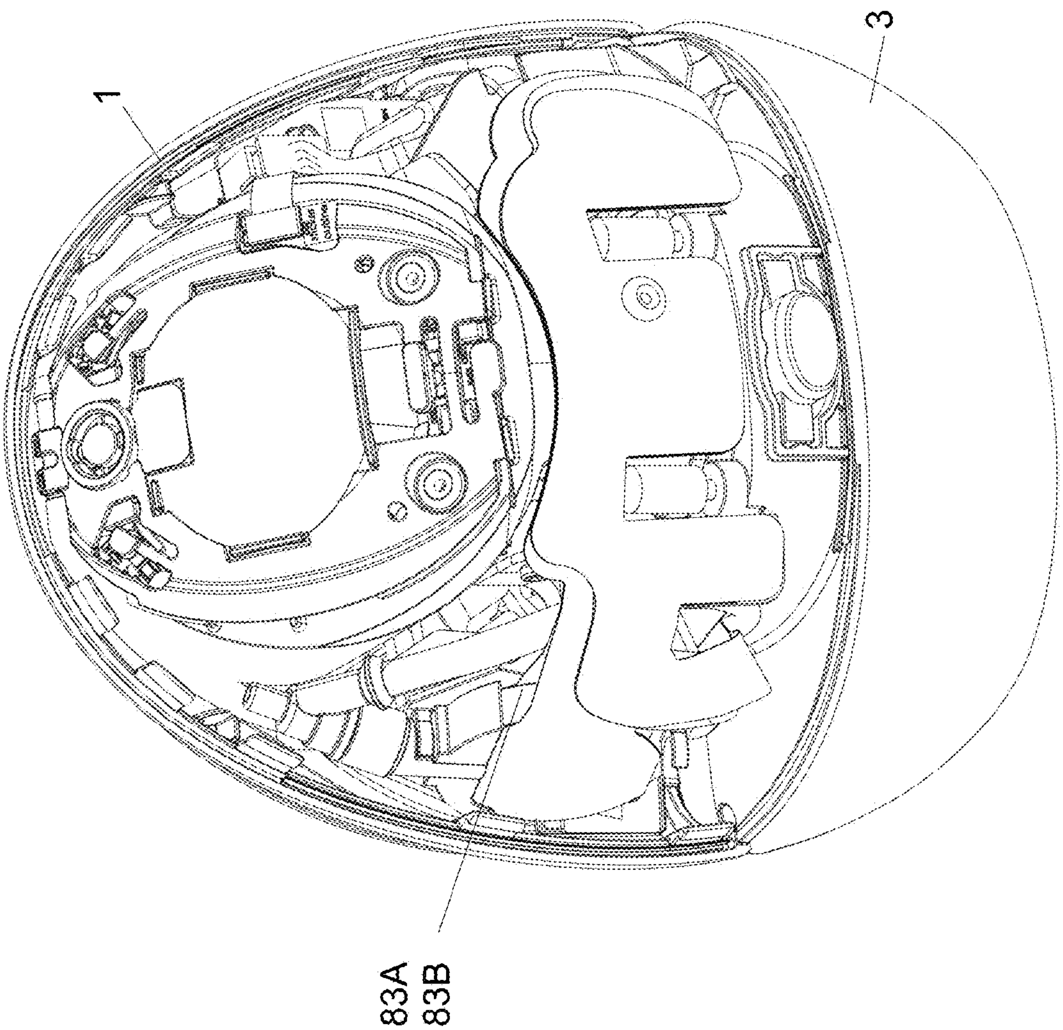

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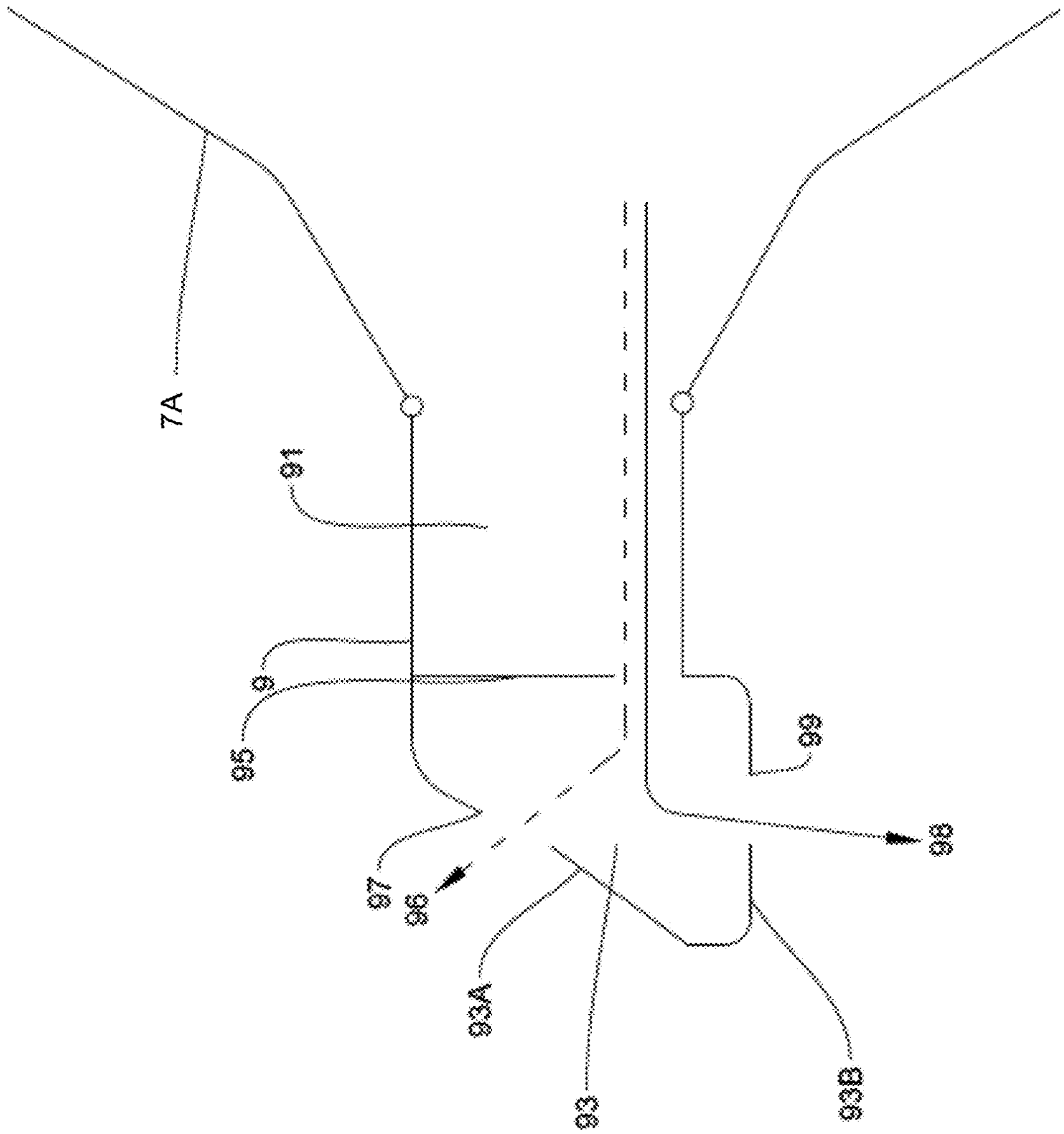

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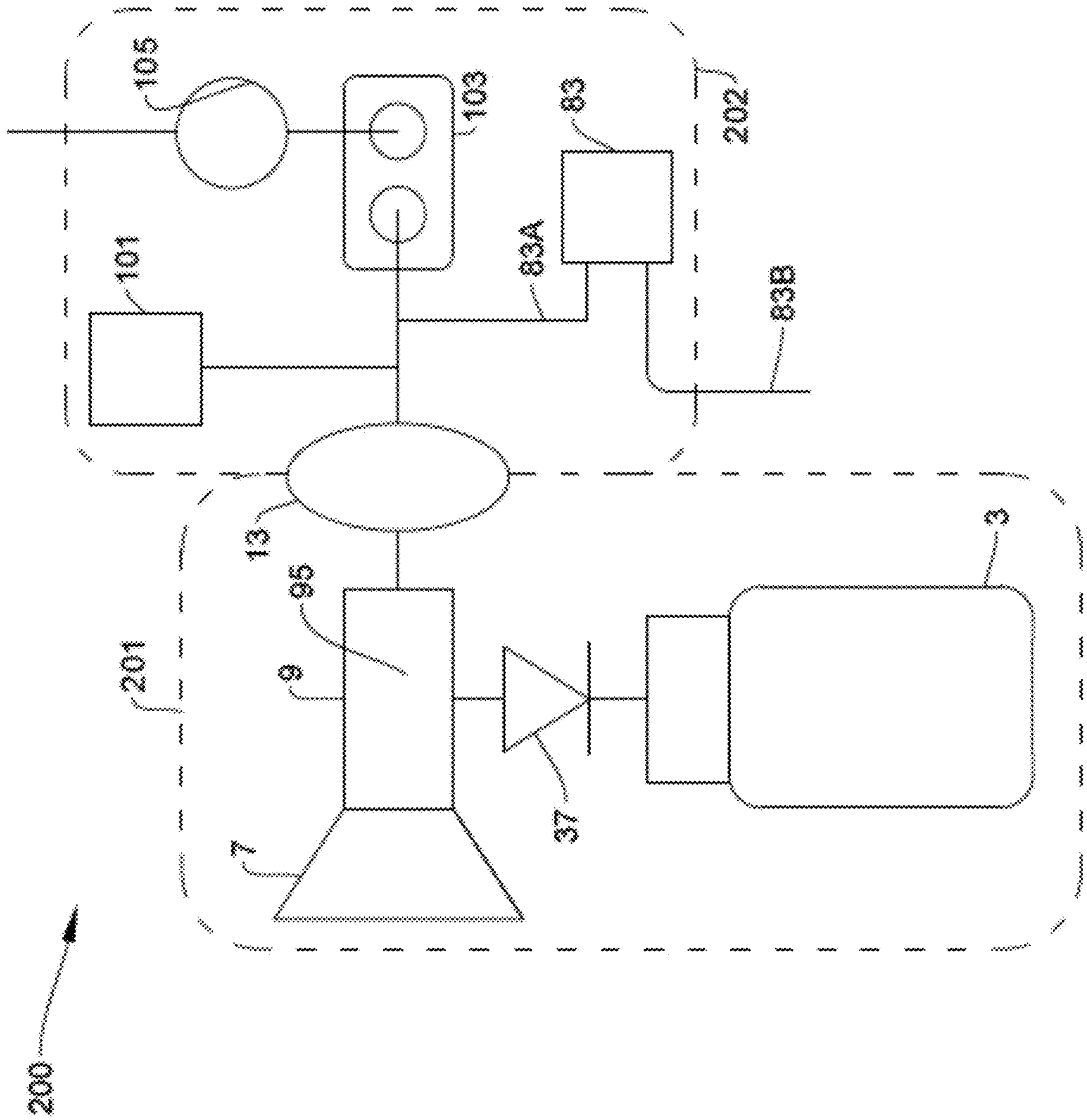

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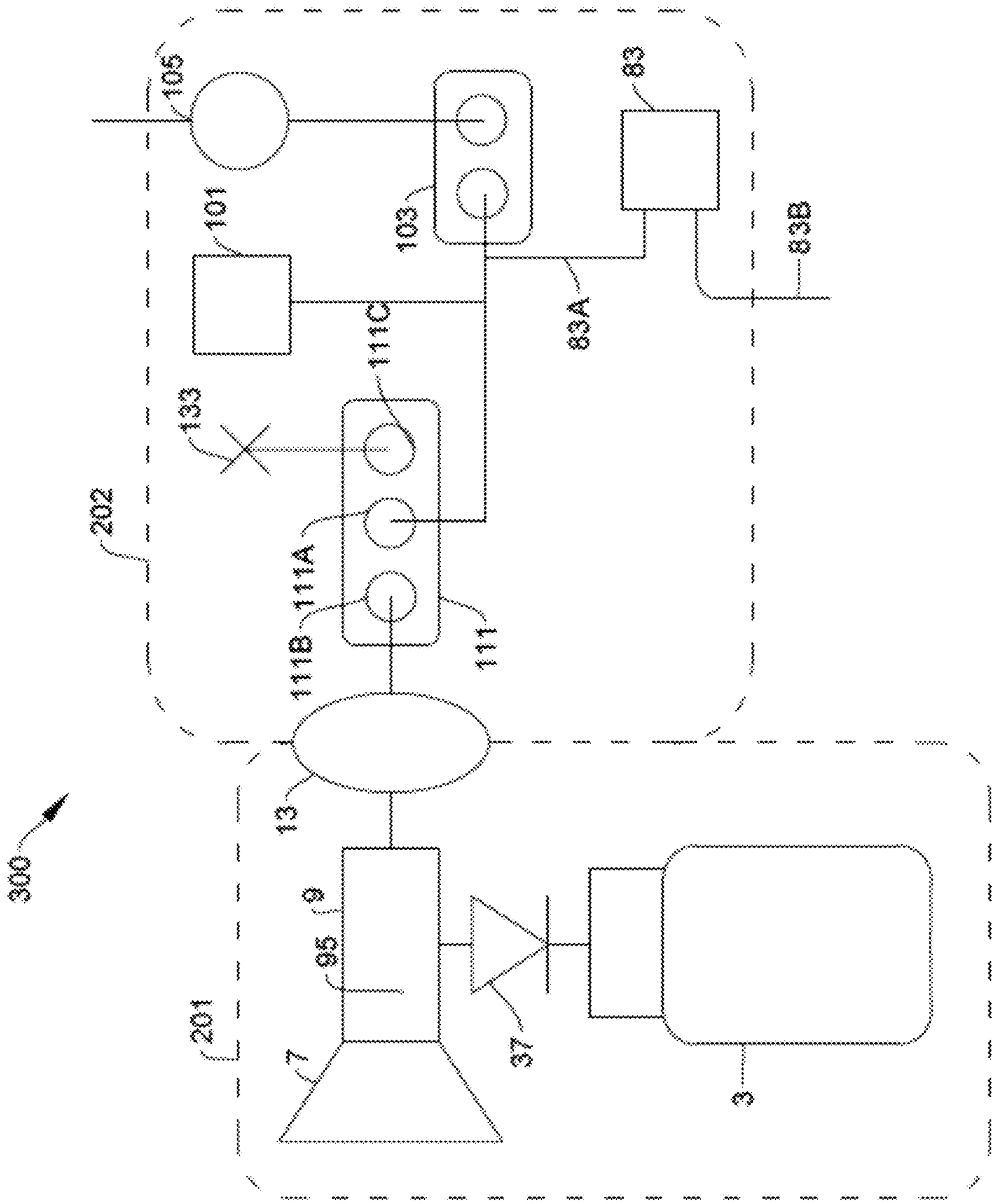
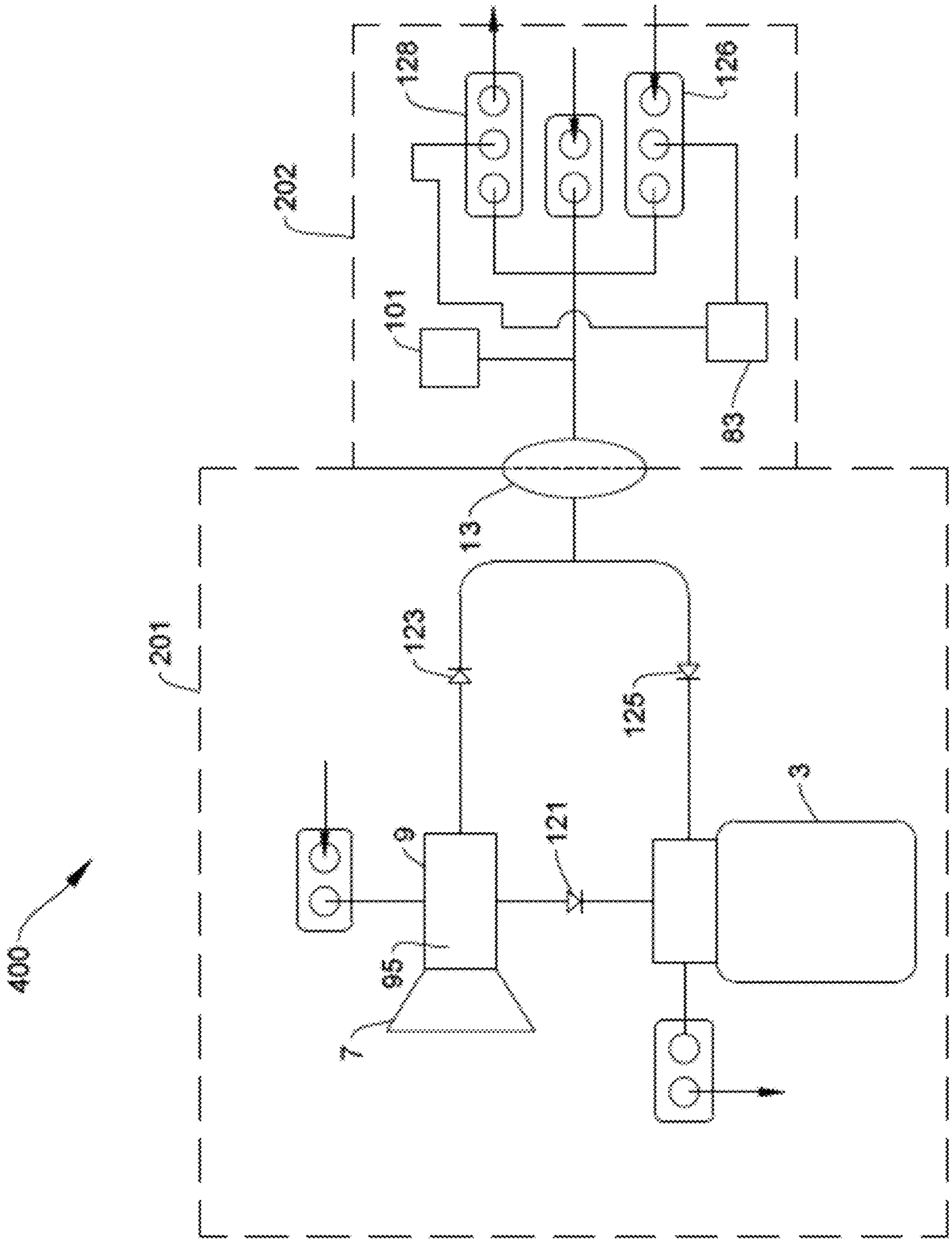

105
101
103
83
83B
83A
111C
133
202
111A
111B
111
13
300
9
95
201
7
37
3

FIGURE 11



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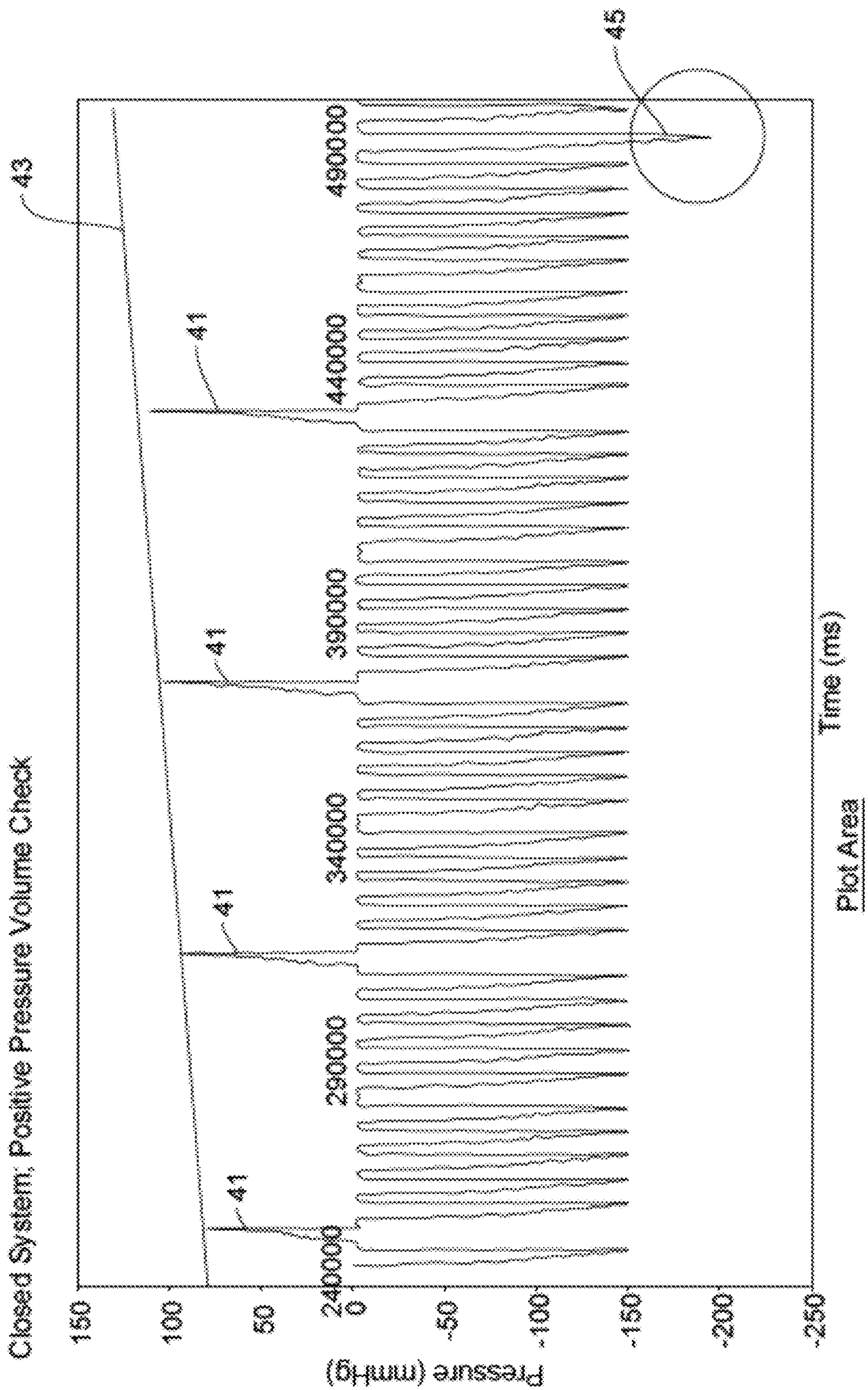
Closed System; Positive Pressure Volume Check
Pressure (mmHg)
150
100
50
0
-50
-100
-150
-200
-250
240000
290000
340000
390000
440000
490000
Time (ms)
Plot Area
41
41
41
41
43
45

FIGURE 13

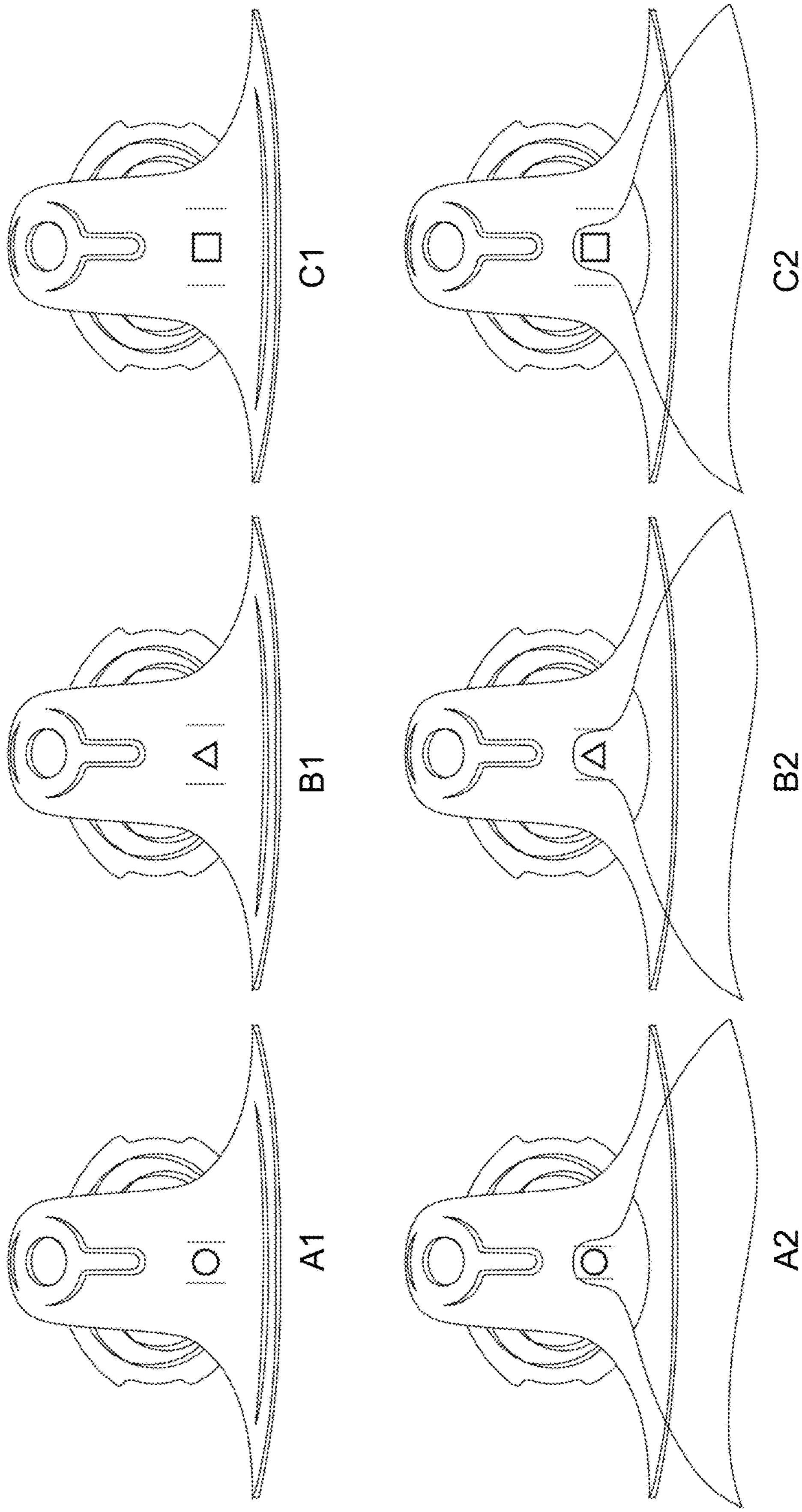

FIGURE 14

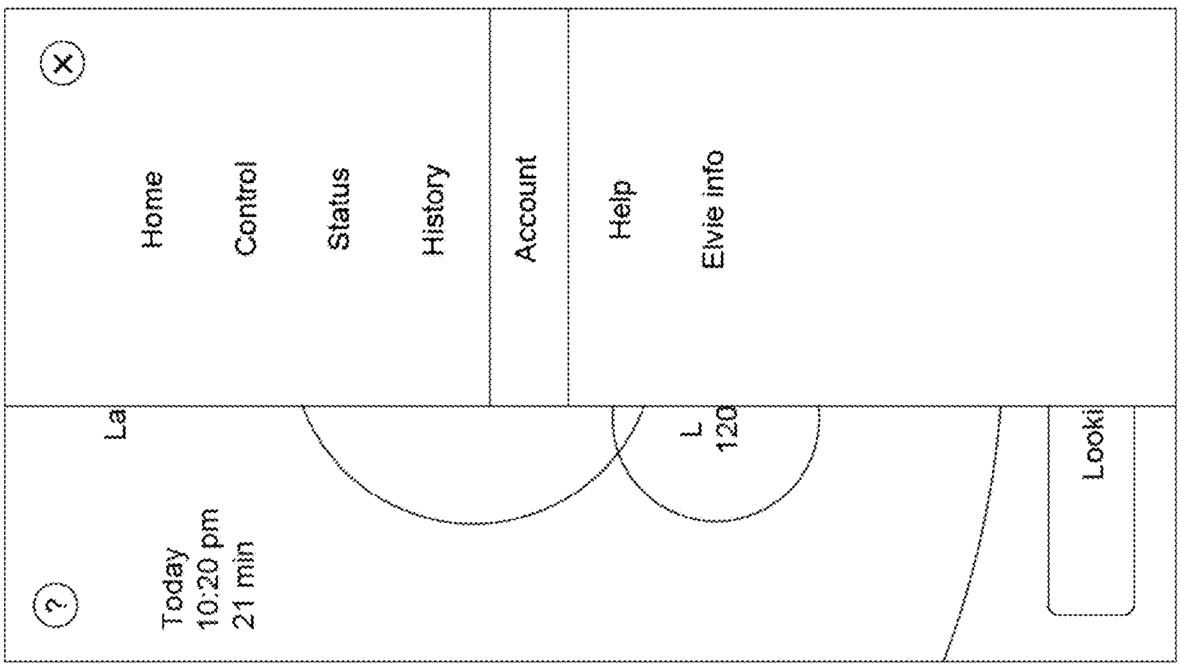
Home
Control
Status
History
Account
Help
Elvie info
La
Today
10:20 pm
21 min
L
120
Looki

FIGURE 15

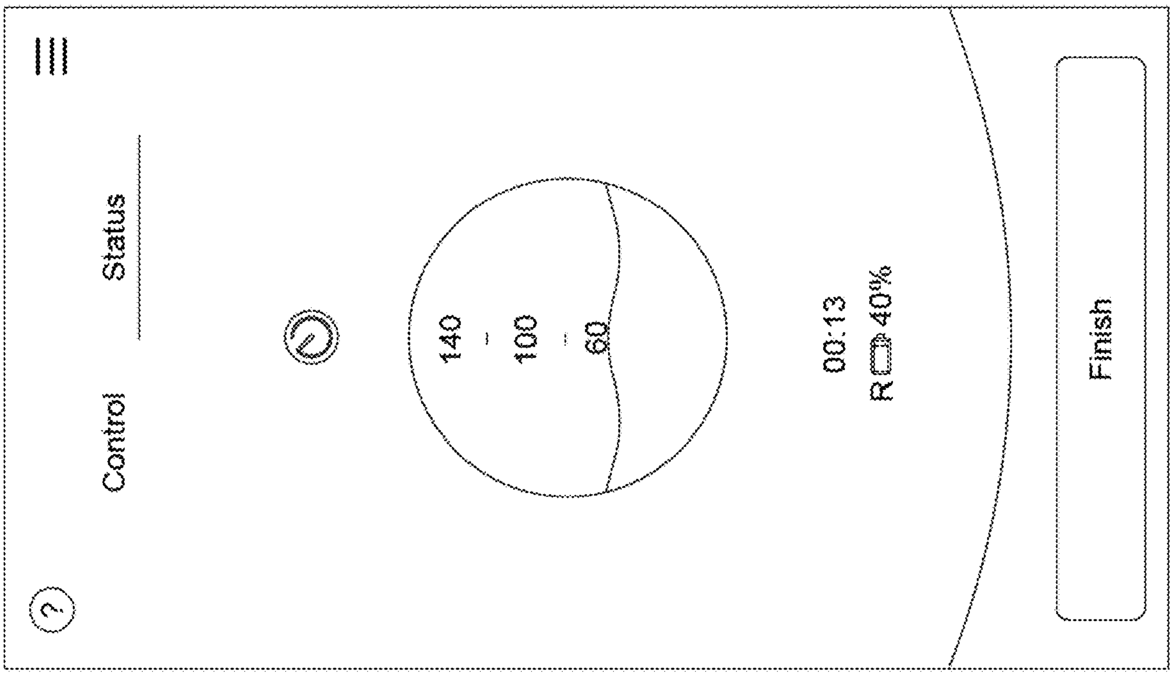

FIGURE 16

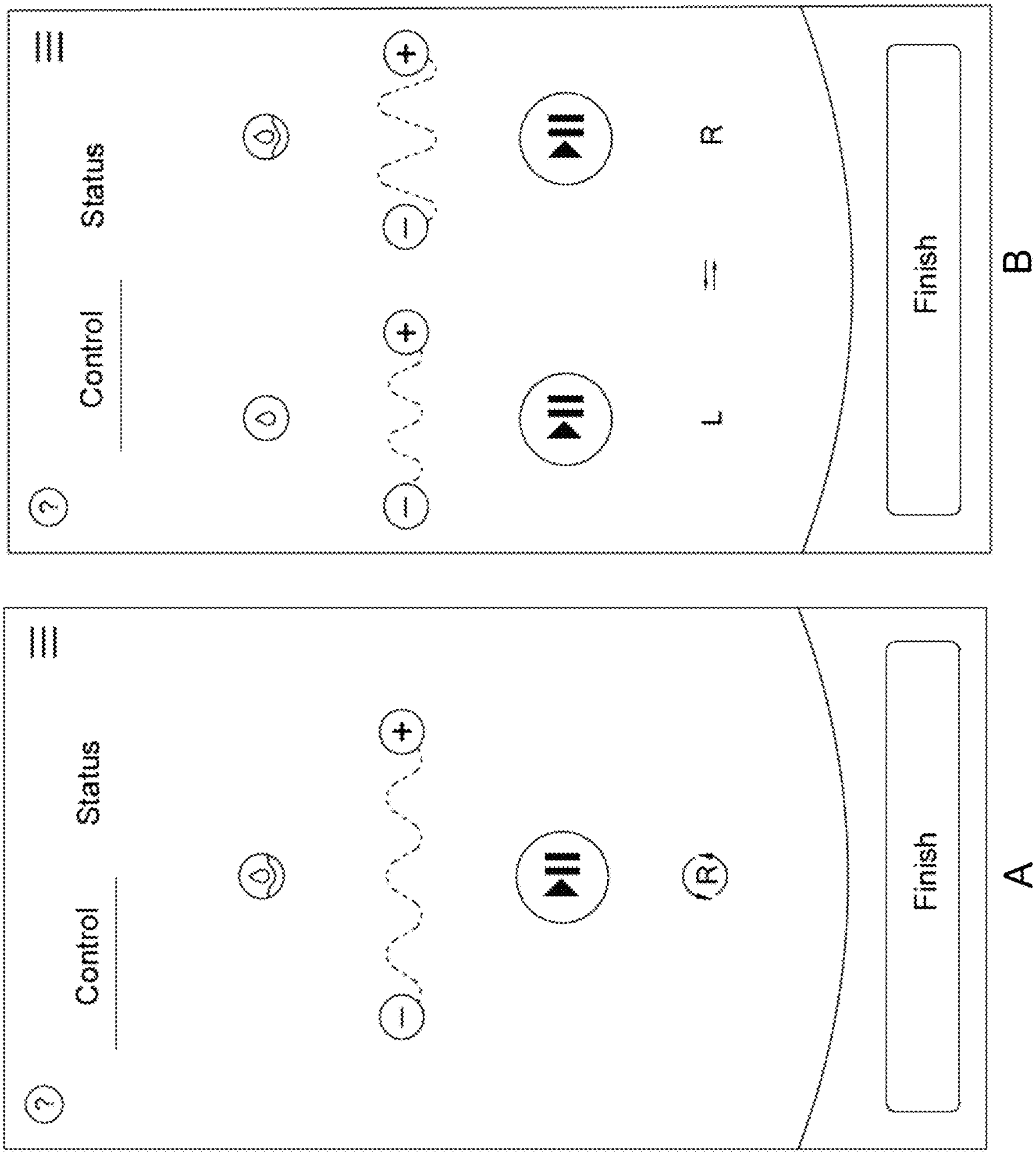

FIGURE 17

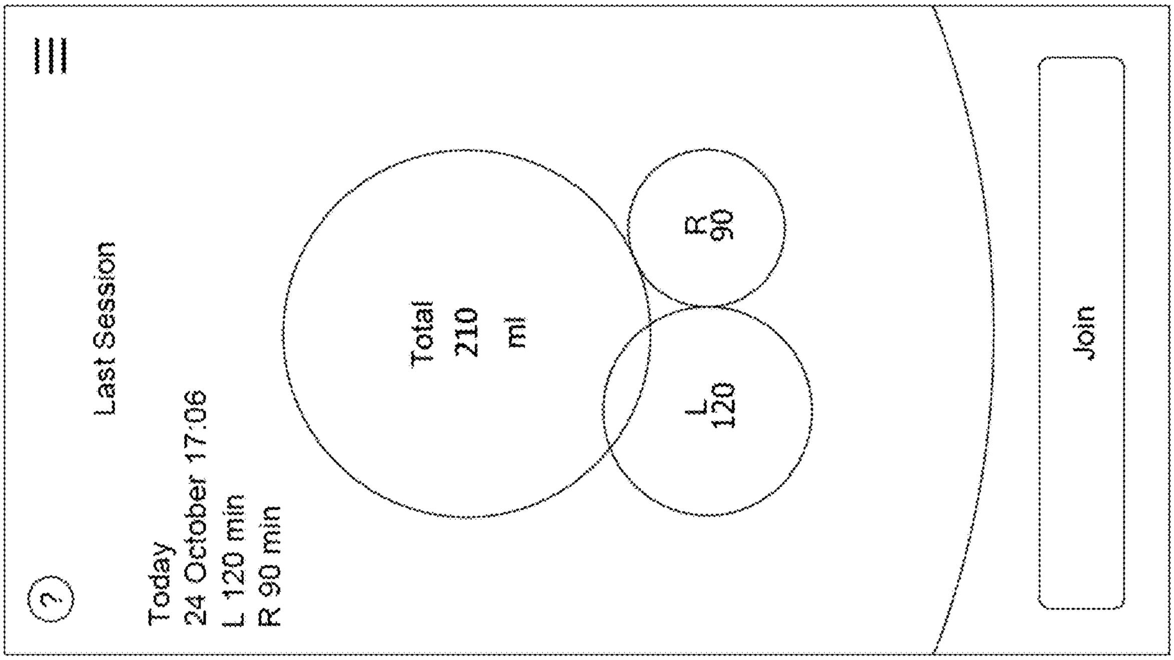
Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
ml
R
90
L
120
Join

FIGURE 18

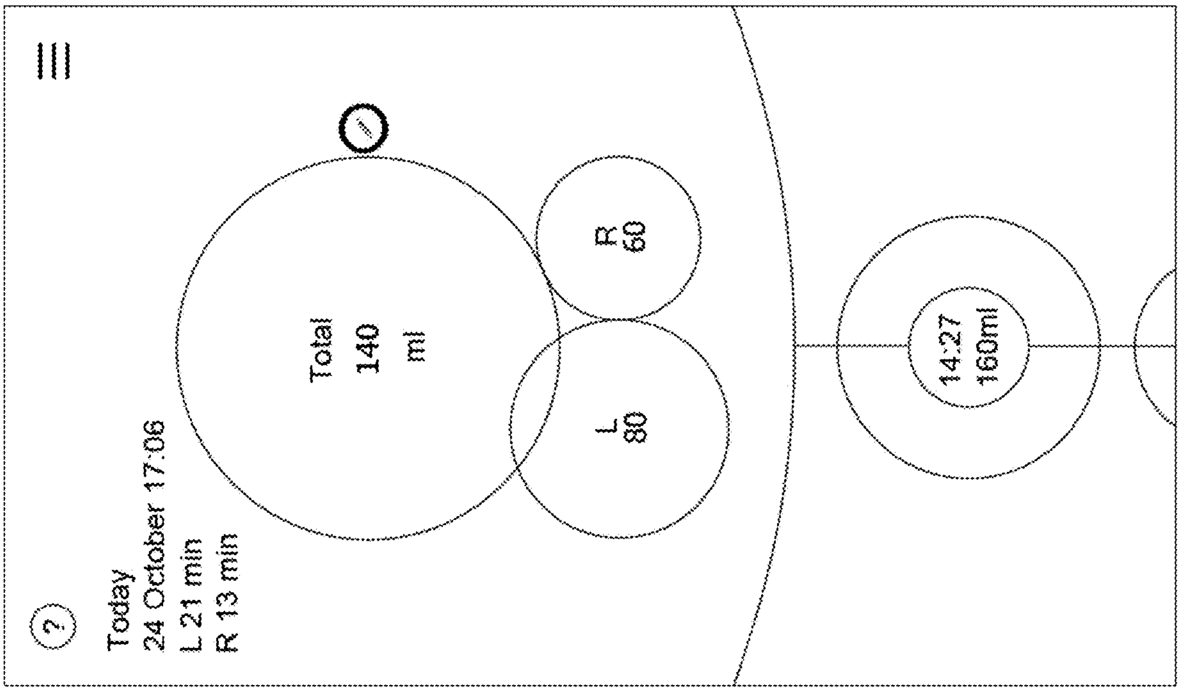
Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
R
60
L
80
14:27
160ml

FIGURE 19

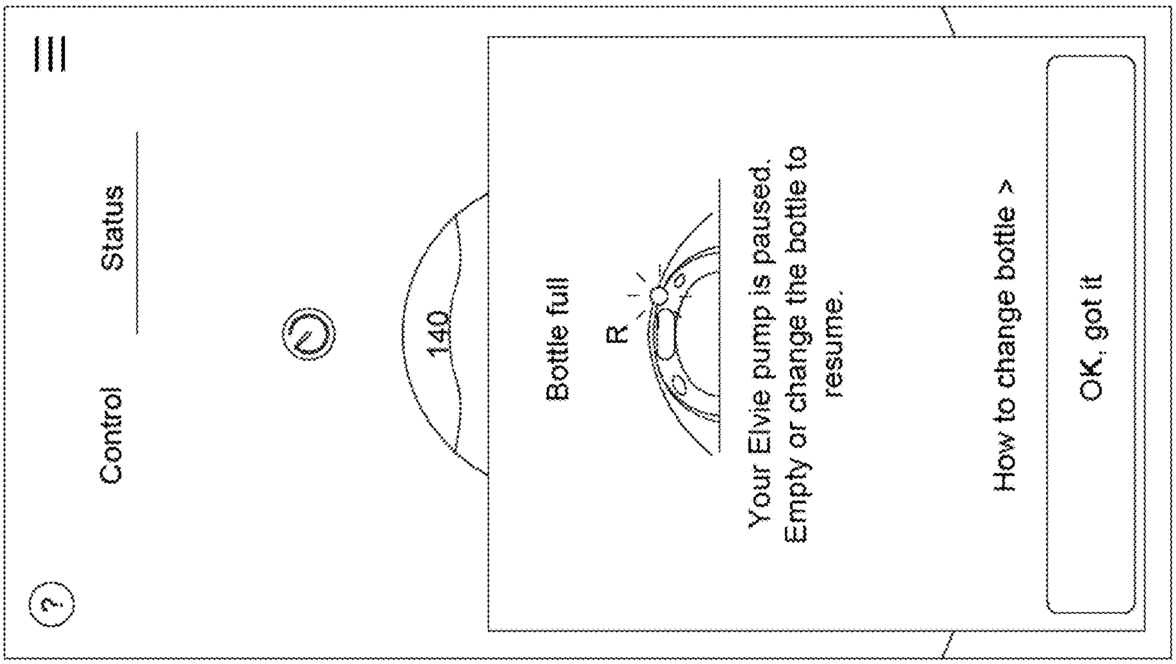
Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to
resume.
How to change bottle >
OK, got it

FIGURE 20

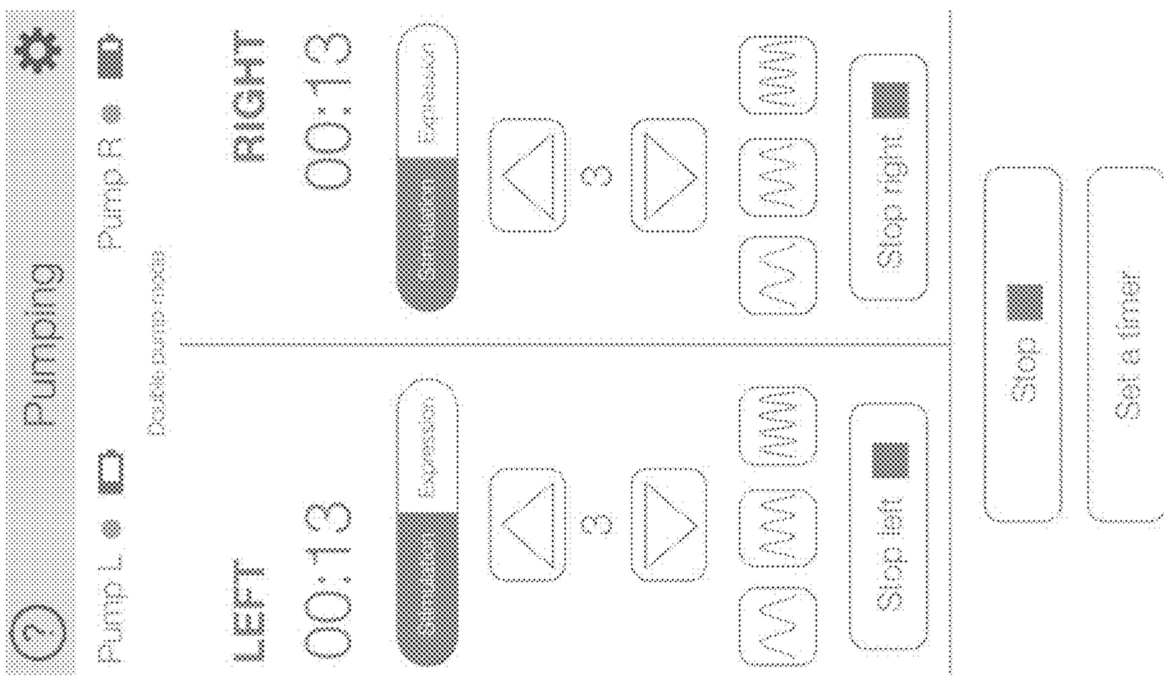
Pumping
Pump L
Pump R
Double pump mode
LEFT
RIGHT
00:13
00:13
Expression
Expression
3
3
Stop left
Stop right
Stop
Set a timer

FIGURE 21

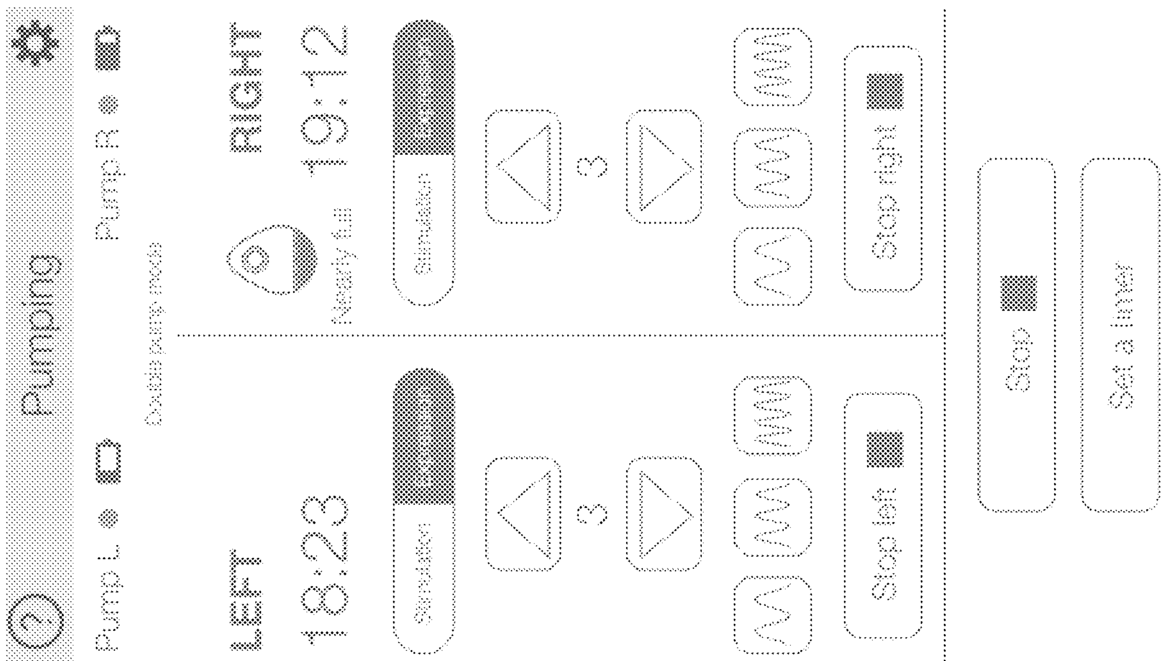
Pumping
Pump L
Pump R
Double pump mode
LEFT
RIGHT
18:23
19:12
Nearly full
Stimulation
Stimulation
3
3
Stop left
Stop right
Stop
Set a timer

FIGURE 22

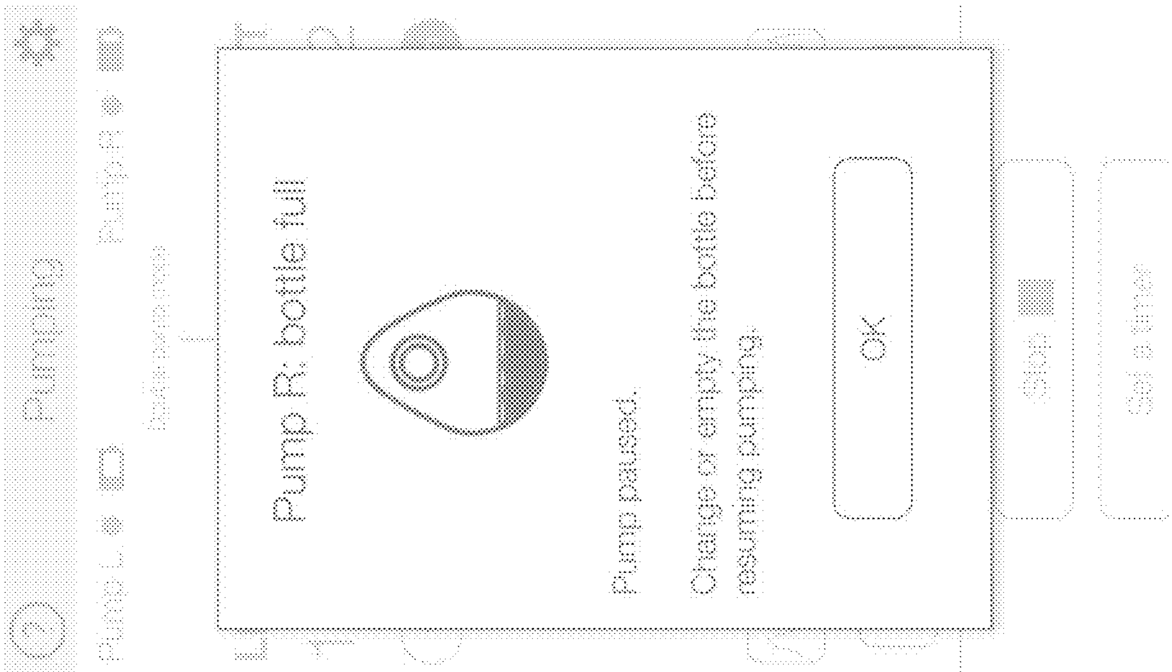
Pumping
Pump L
Pump R
Pump R: bottle full
Pump paused.
Charge or empty the bottle before resuming pumping.
OK
Stop
Set a timer

FIGURE 23


Stopped
Pump L
Pump R
Double pump mode
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle:
60 ml
Total volume in bottle:
65 ml
Tick if you emptied or changed the bottle
Tick if you emptied or changed the bottle
Resume left
Resume right
Resume
End session

FIGURE 24

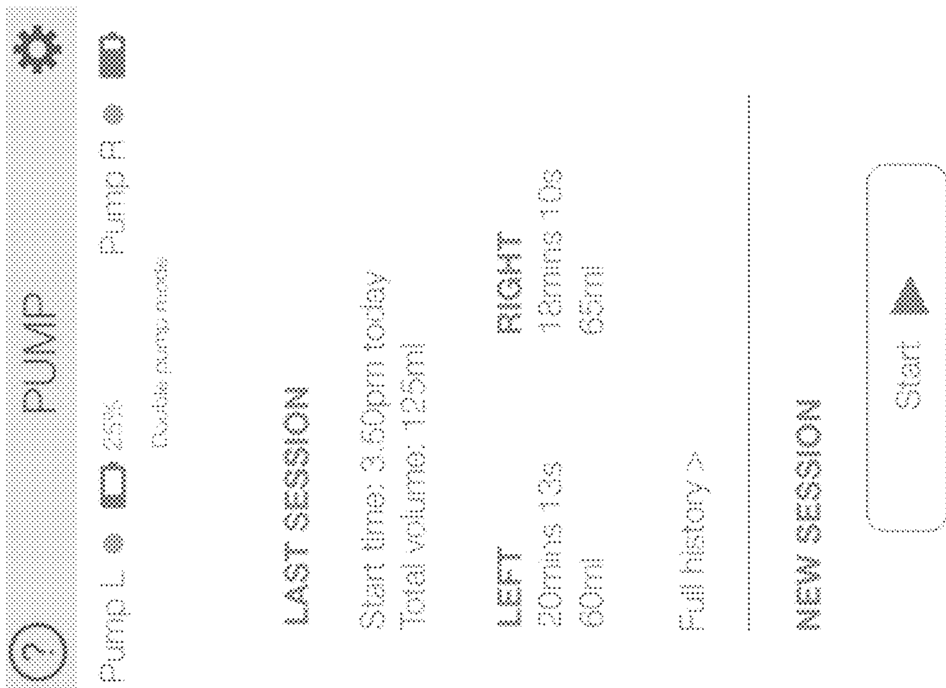
PUMP
Pump L
25%
Pump R
Double pump mode
LAST SESSION
Start time: 3.50pm today
Total volume: 125ml
LEFT
20mins 13s
60ml
RIGHT
18mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

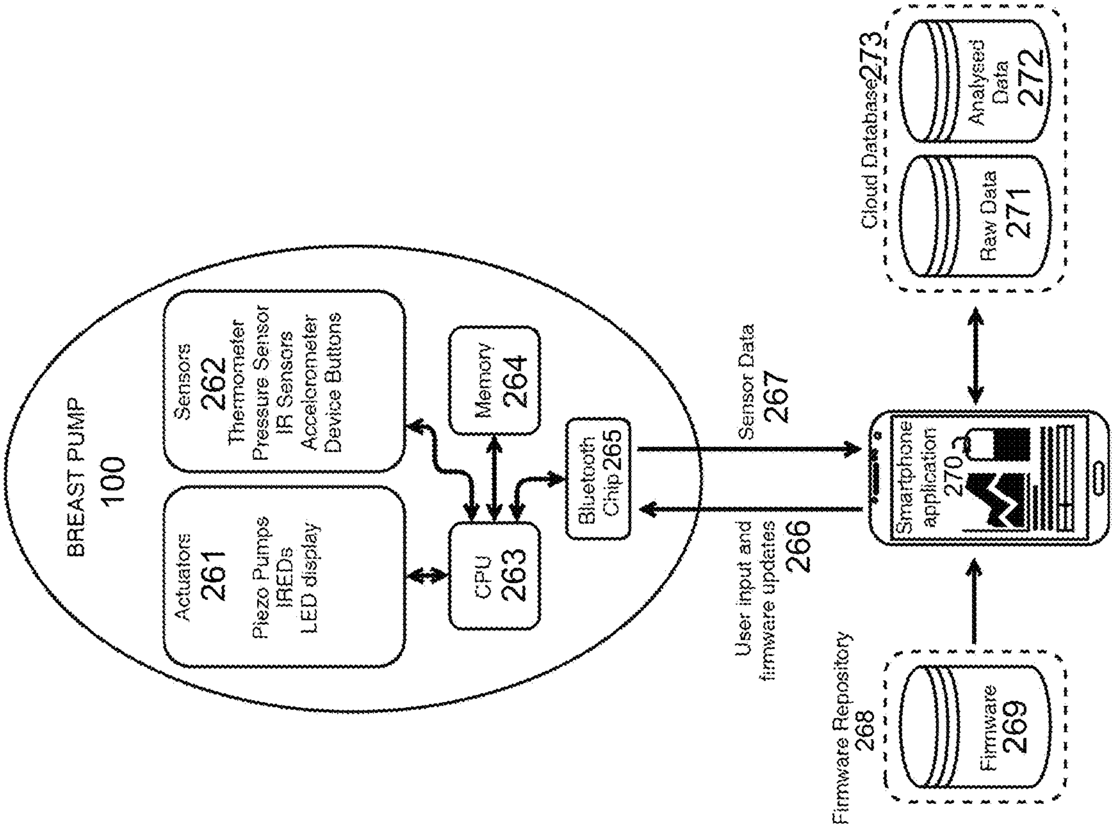
BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelerometer
Device Buttons
CPU
263
Memory
264
Bluetooth
Chip 265
Sensor Data
267
User input and
firmware updates
266
Smartphone
application
270
Cloud Database 273
Raw Data
271
Analysed
Data
272
Firmware Repository
268
Firmware
269

FIGURE 26

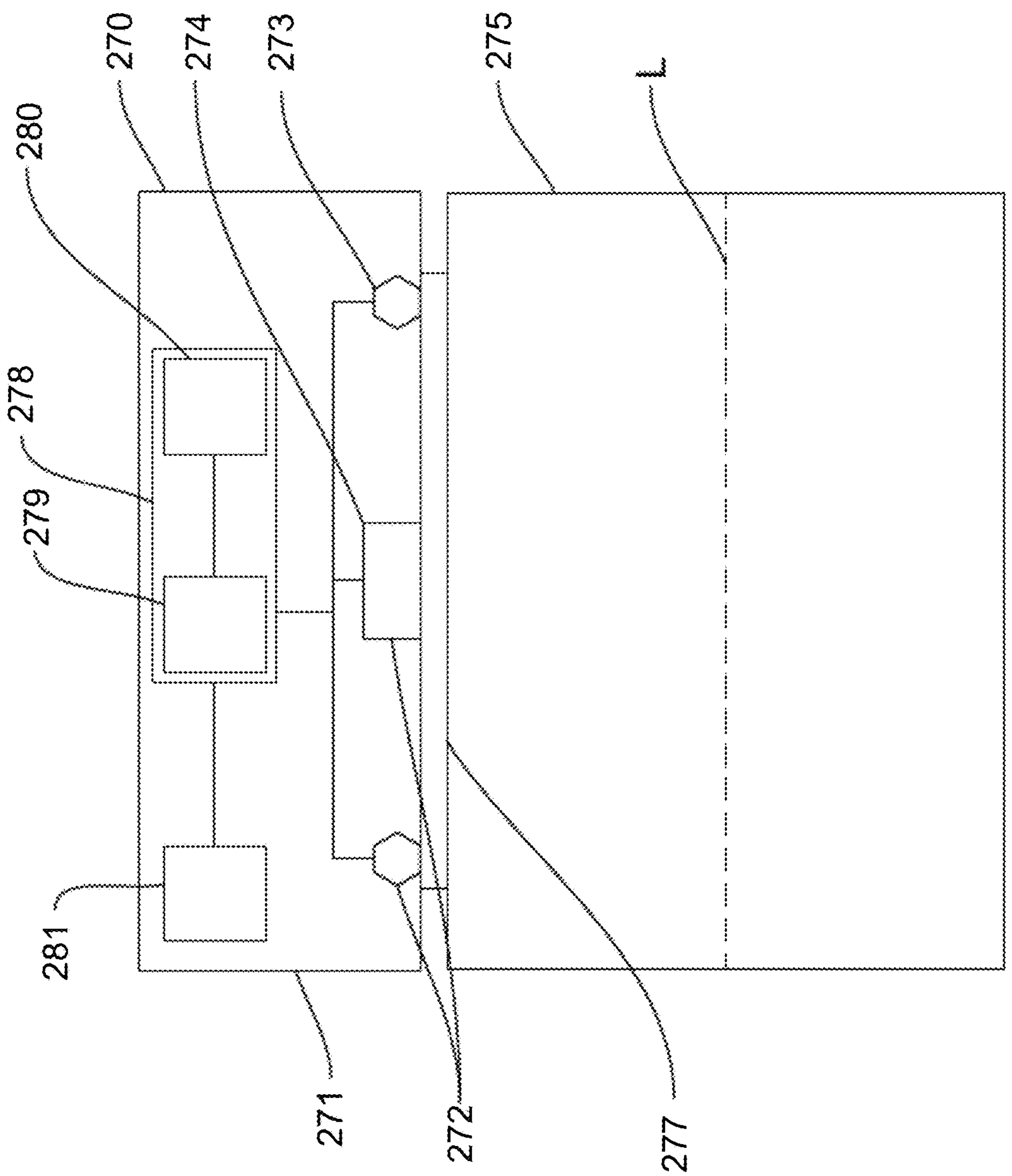

FIGURE 27

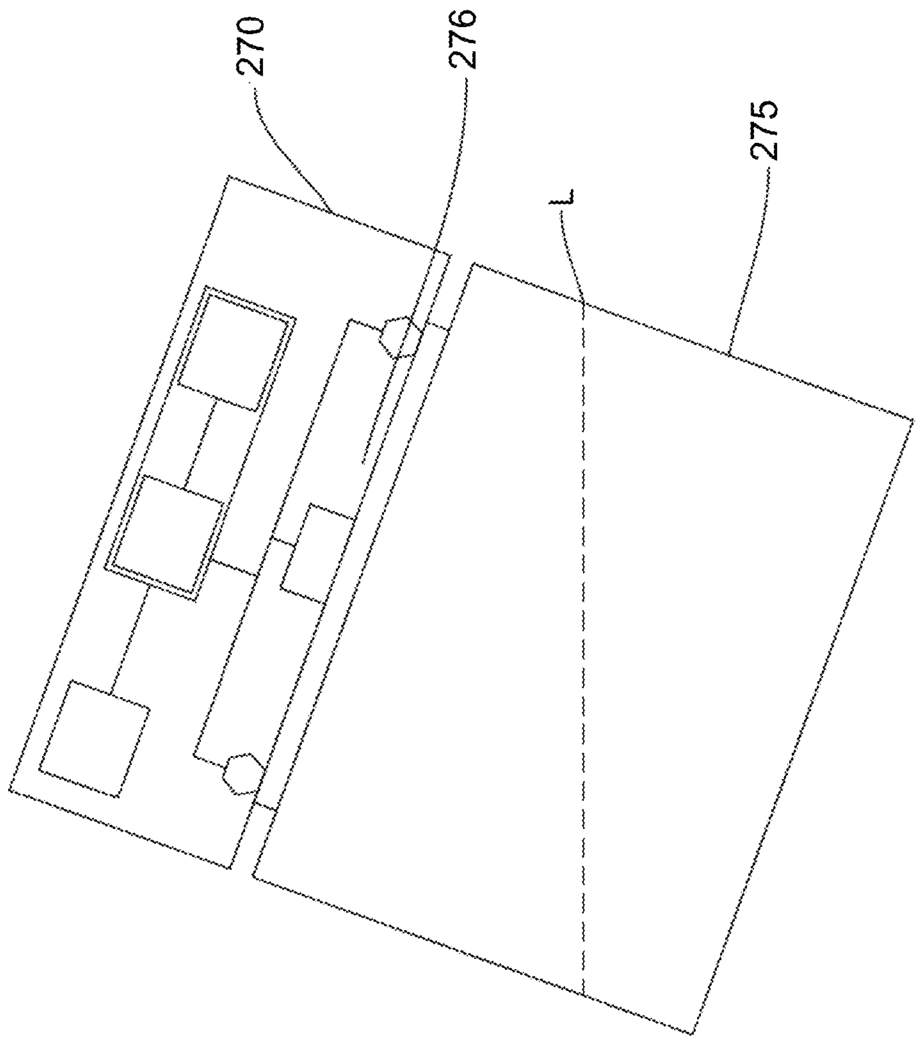

FIGURE 28

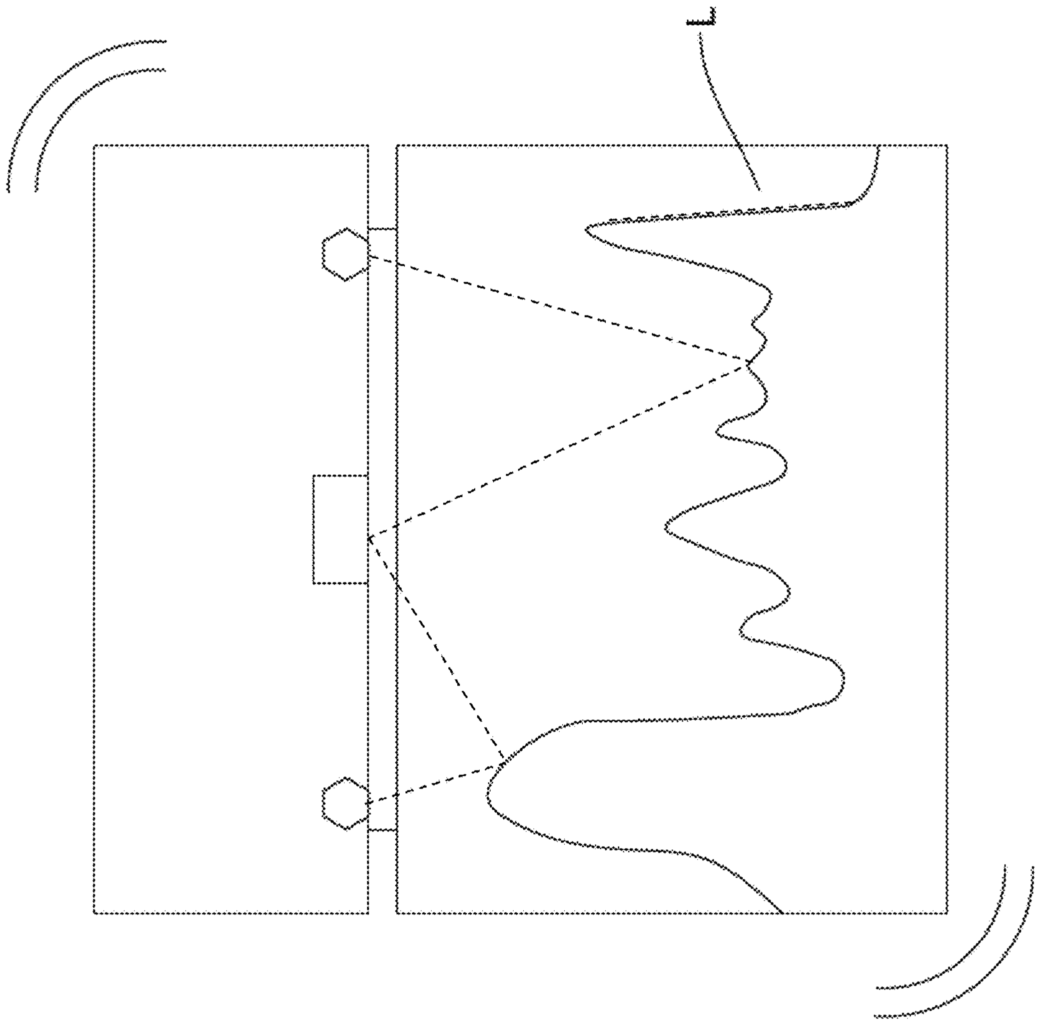

FIGURE 29

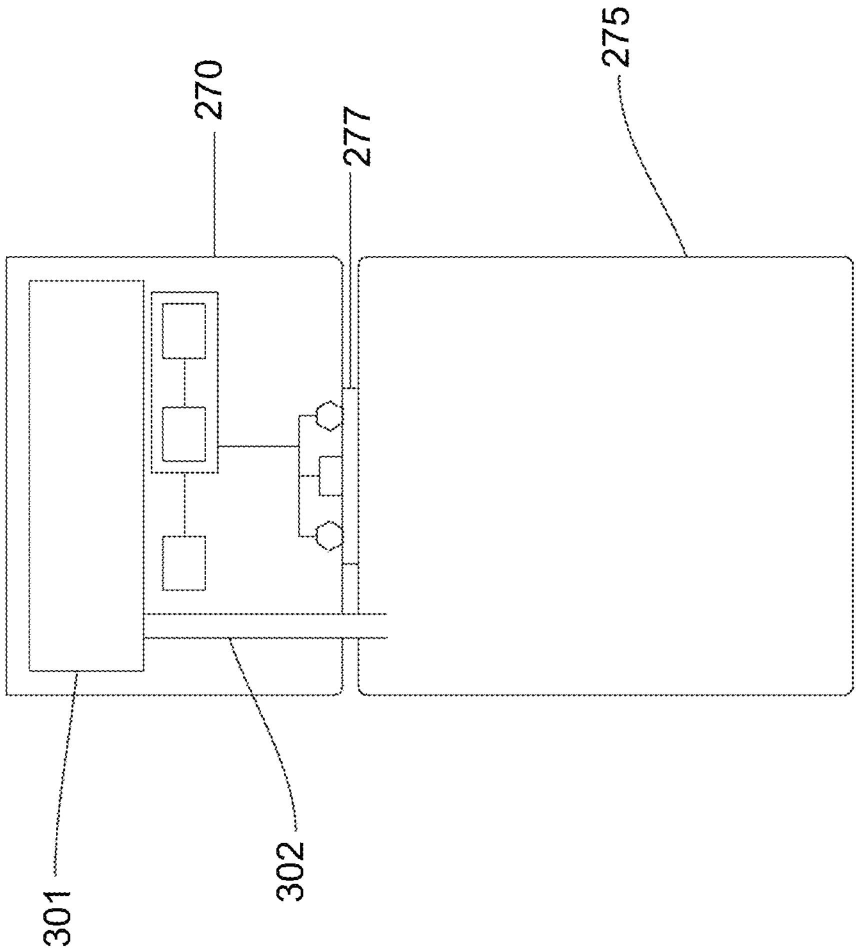

FIGURE 30

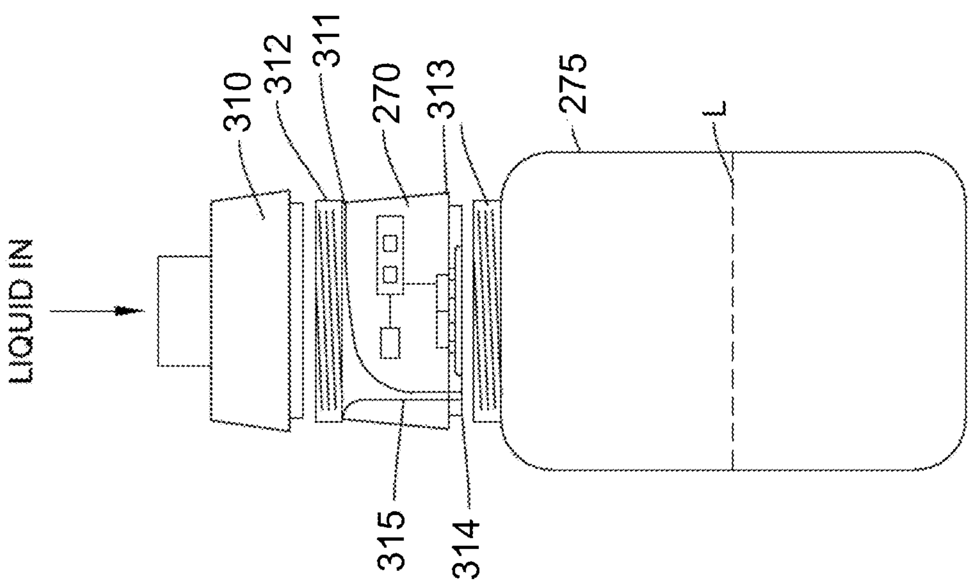

FIGURE 31

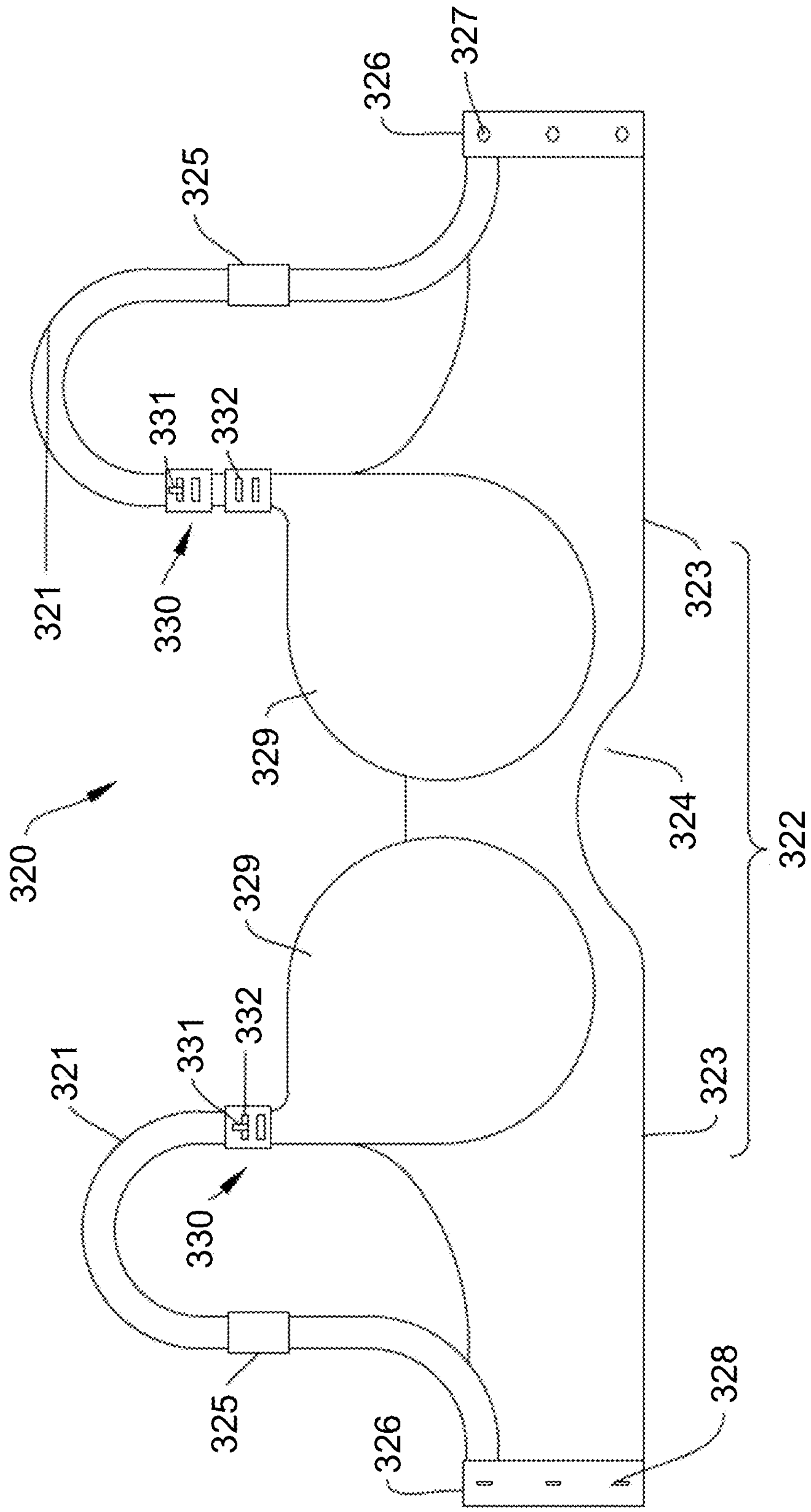
327
326
325
331
332
321
330
323
329
320
324
322
329
321
331
332
323
330
325
326
328

FIGURE 32

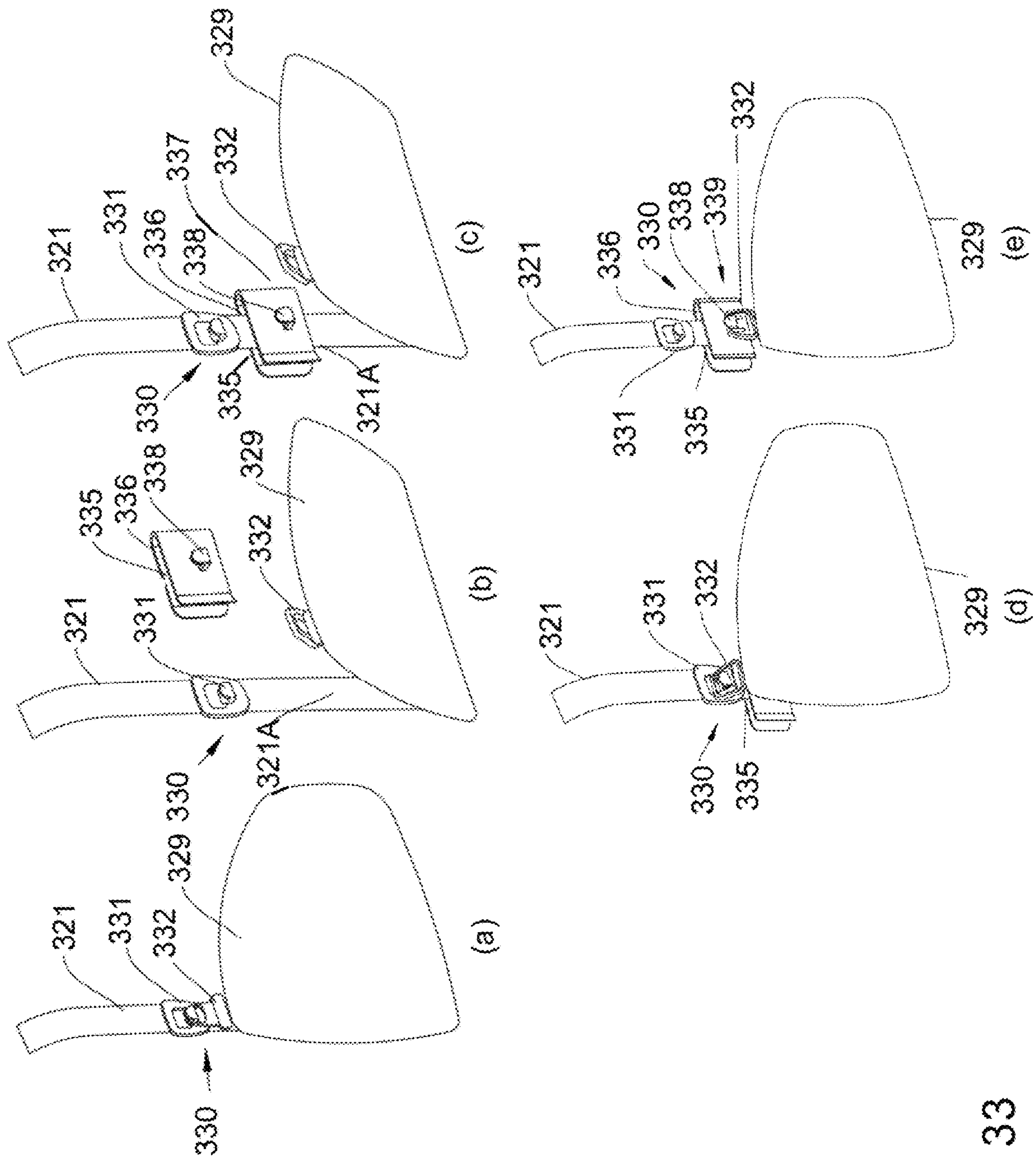

FIGURE 33

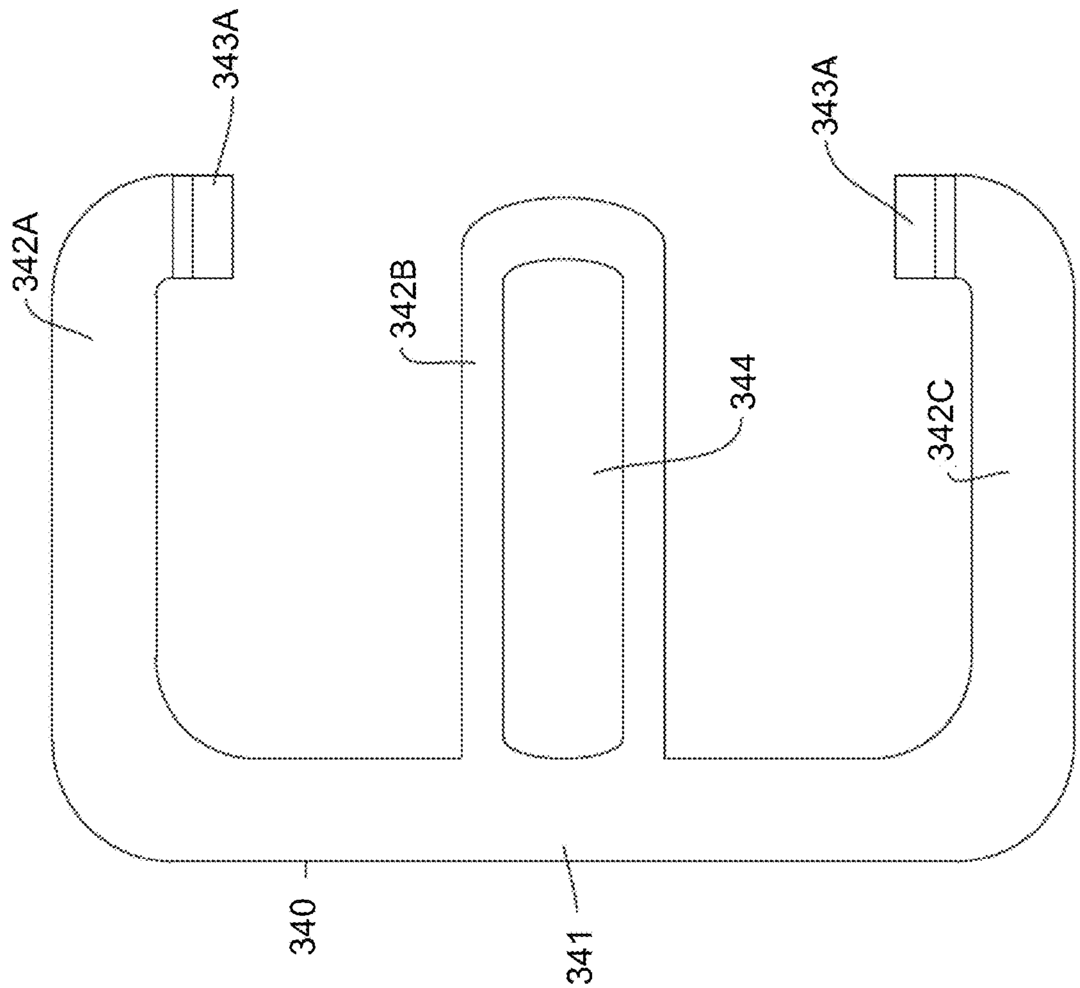

FIGURE 34

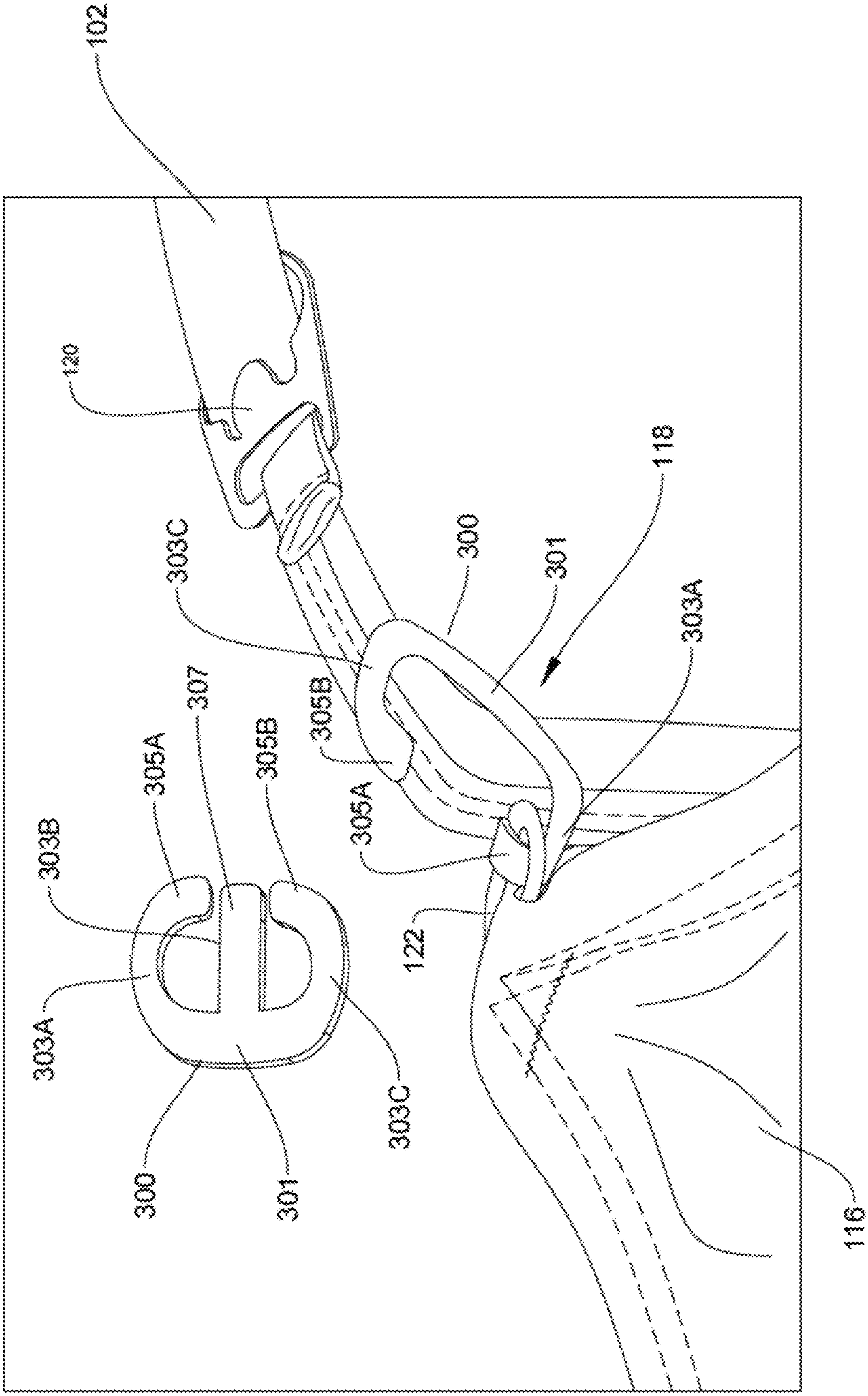

FIGURE 35

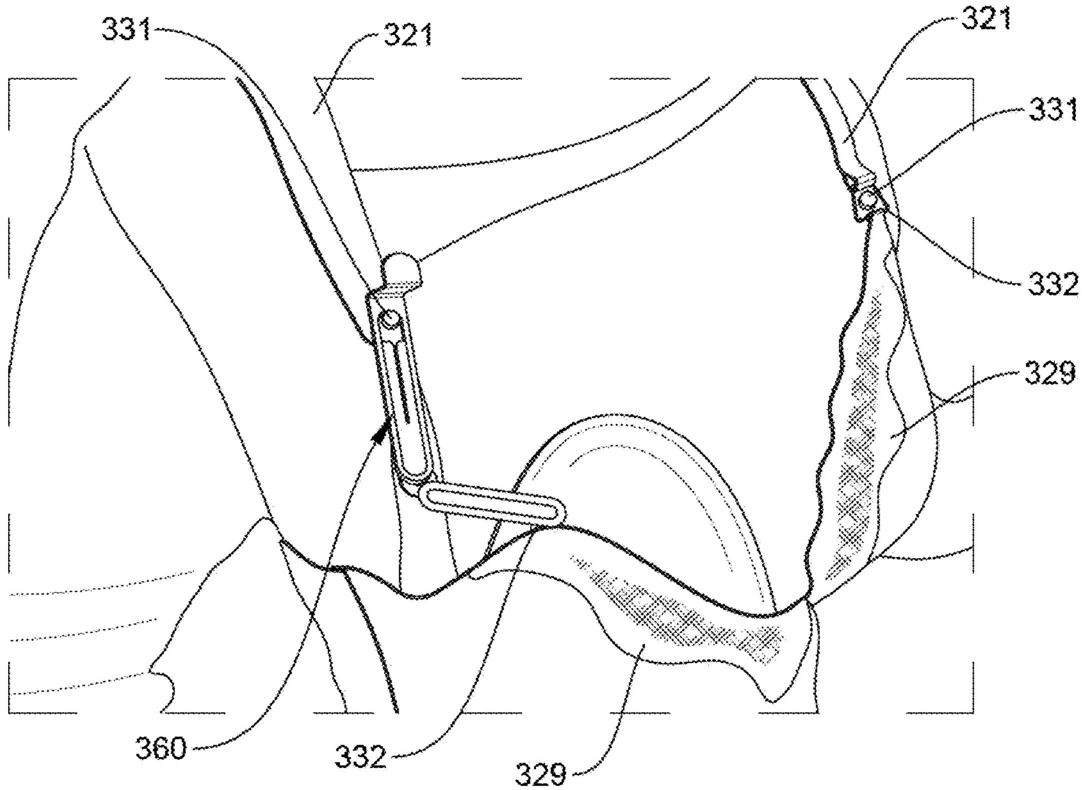

FIGURE 36

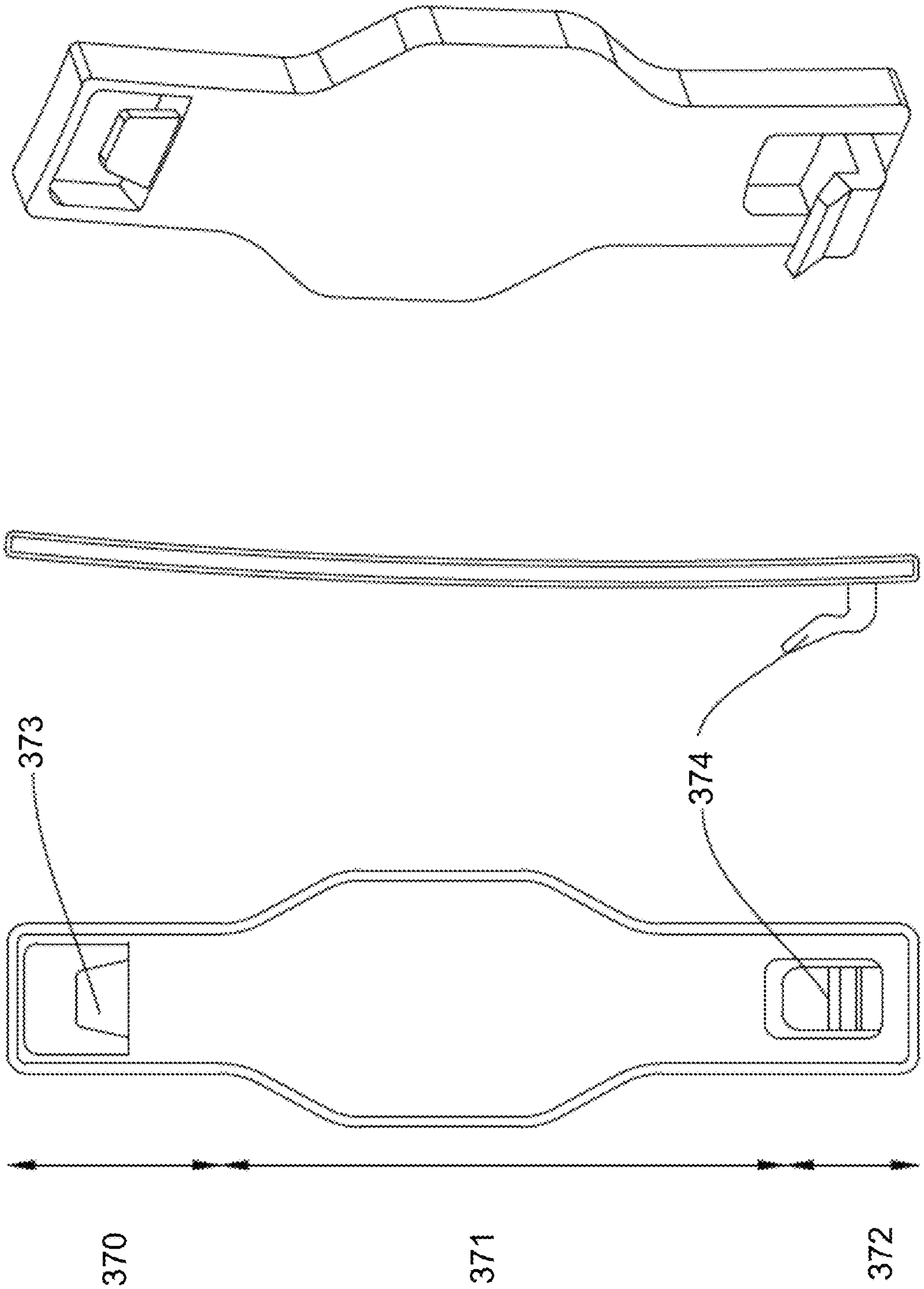

FIGURE 37

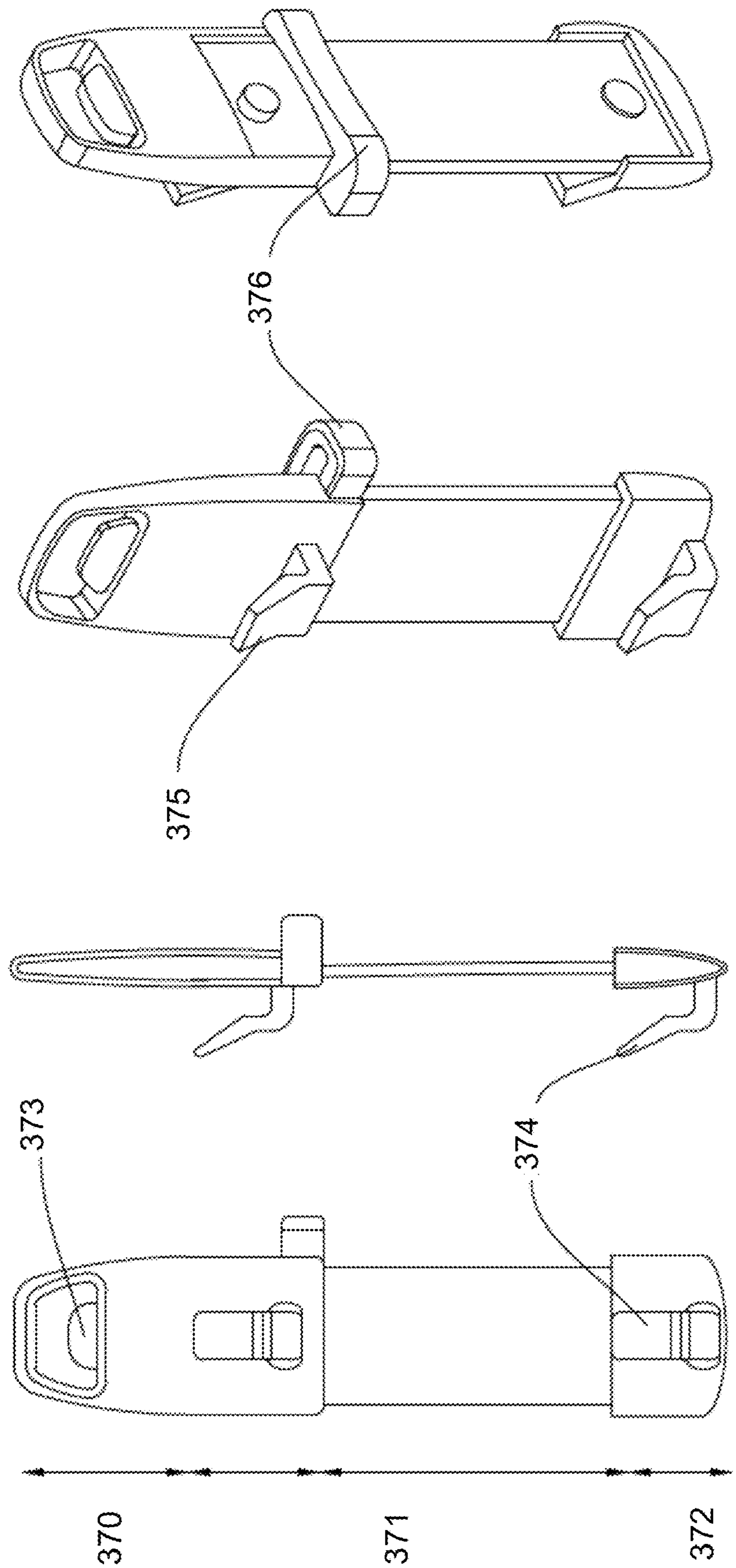

FIGURE 38

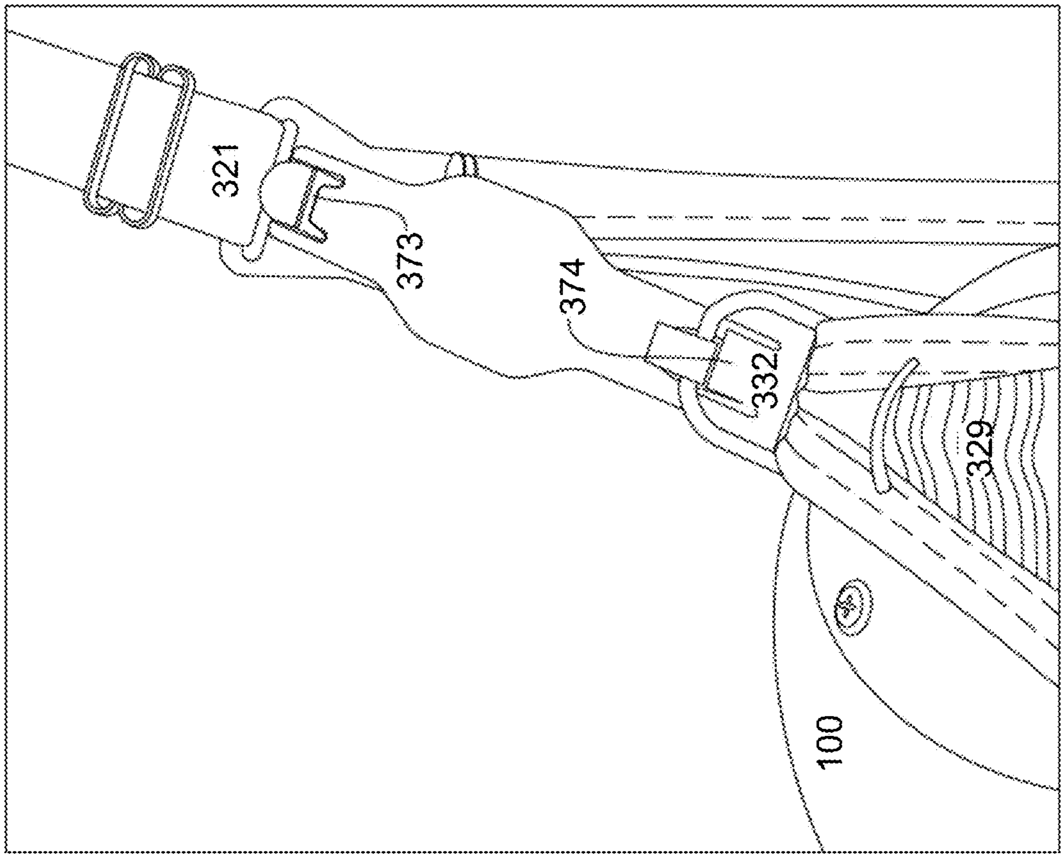

FIGURE 39

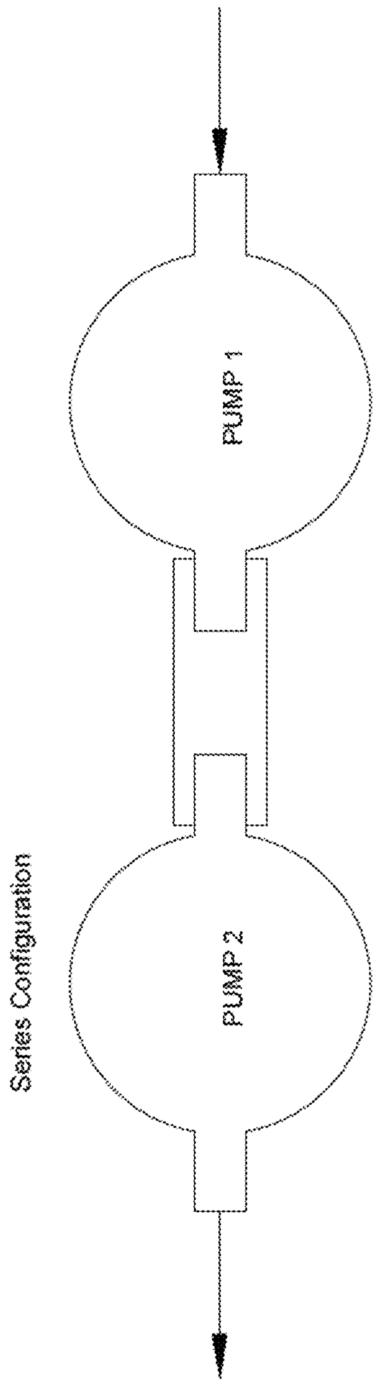

FIGURE 40

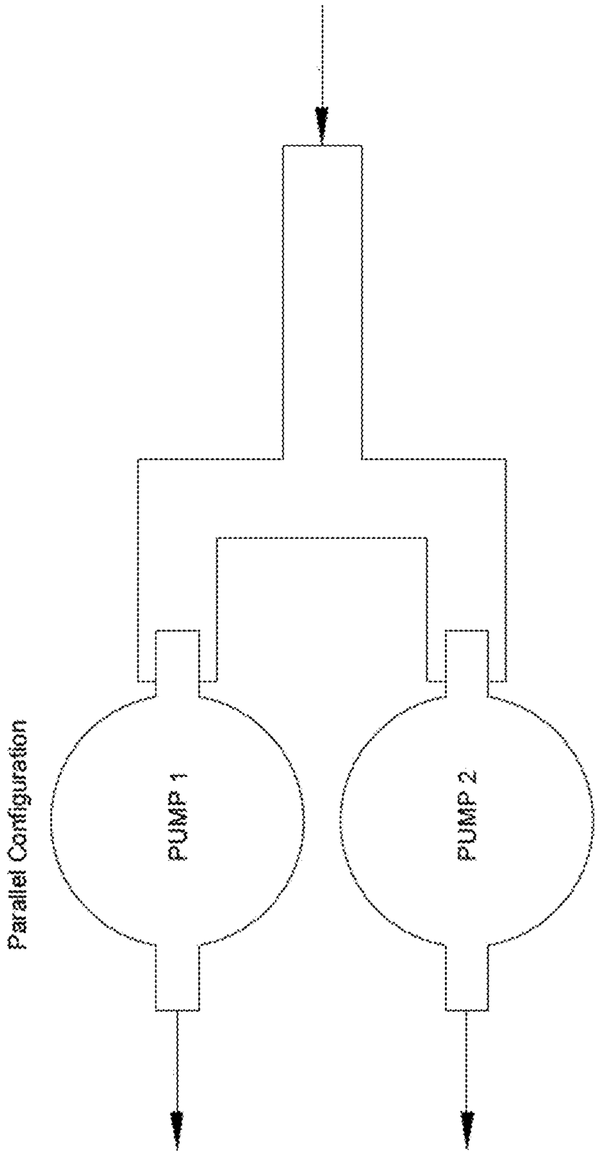

FIGURE 41

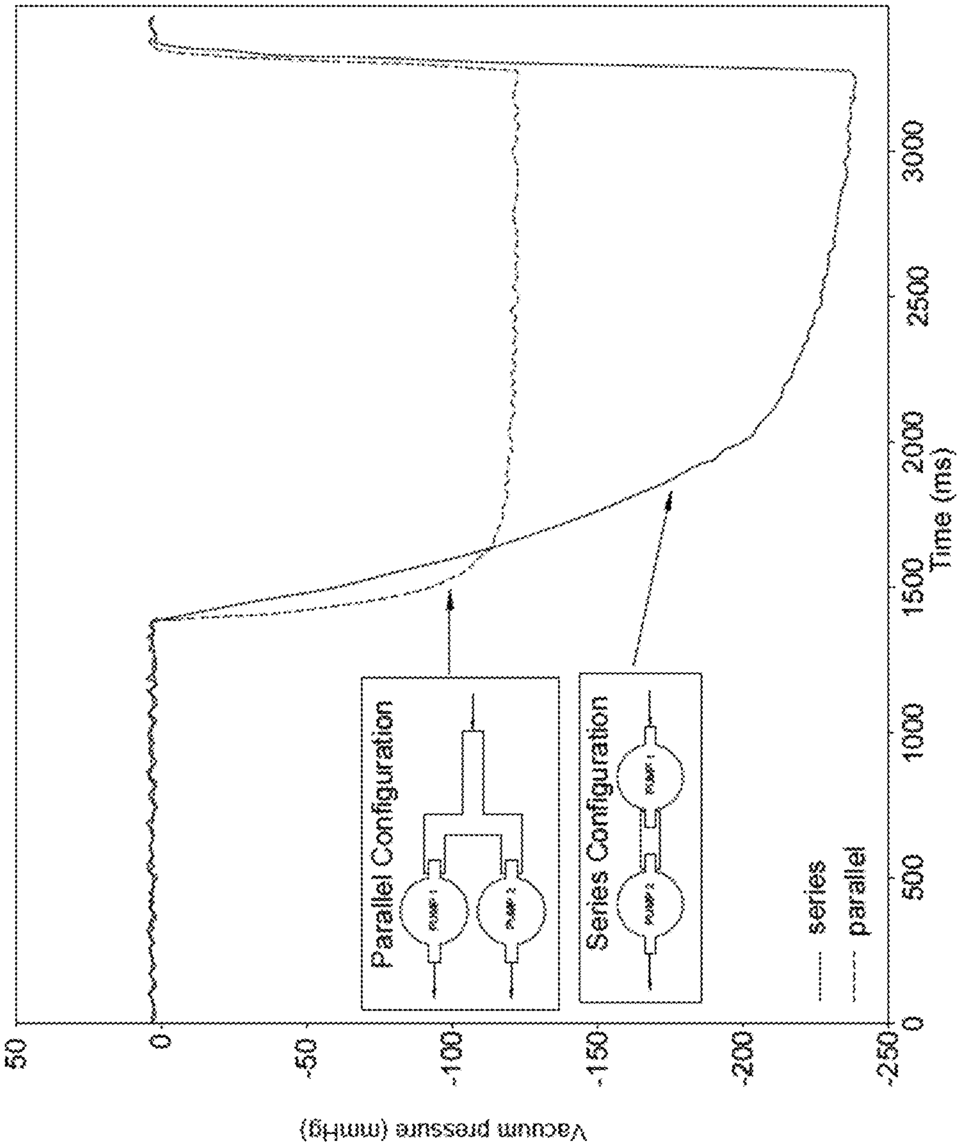
Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
Time (ms)
0
500
1000
1500
2000
2500
3000
Parallel Configuration
Series Configuration
series
parallel

FIGURE 42

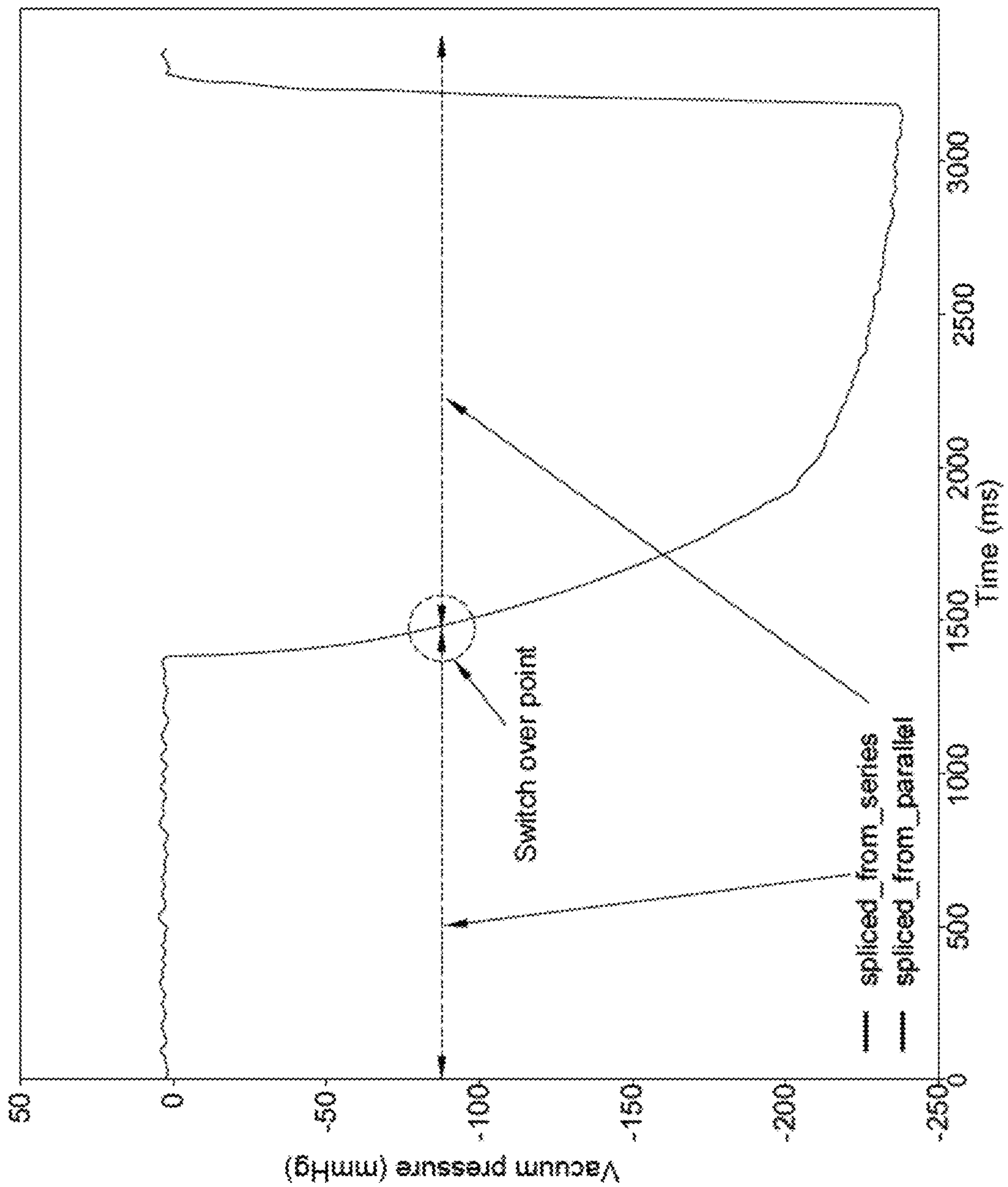
Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
Time (ms)
0
500
1000
1500
2000
2500
3000
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

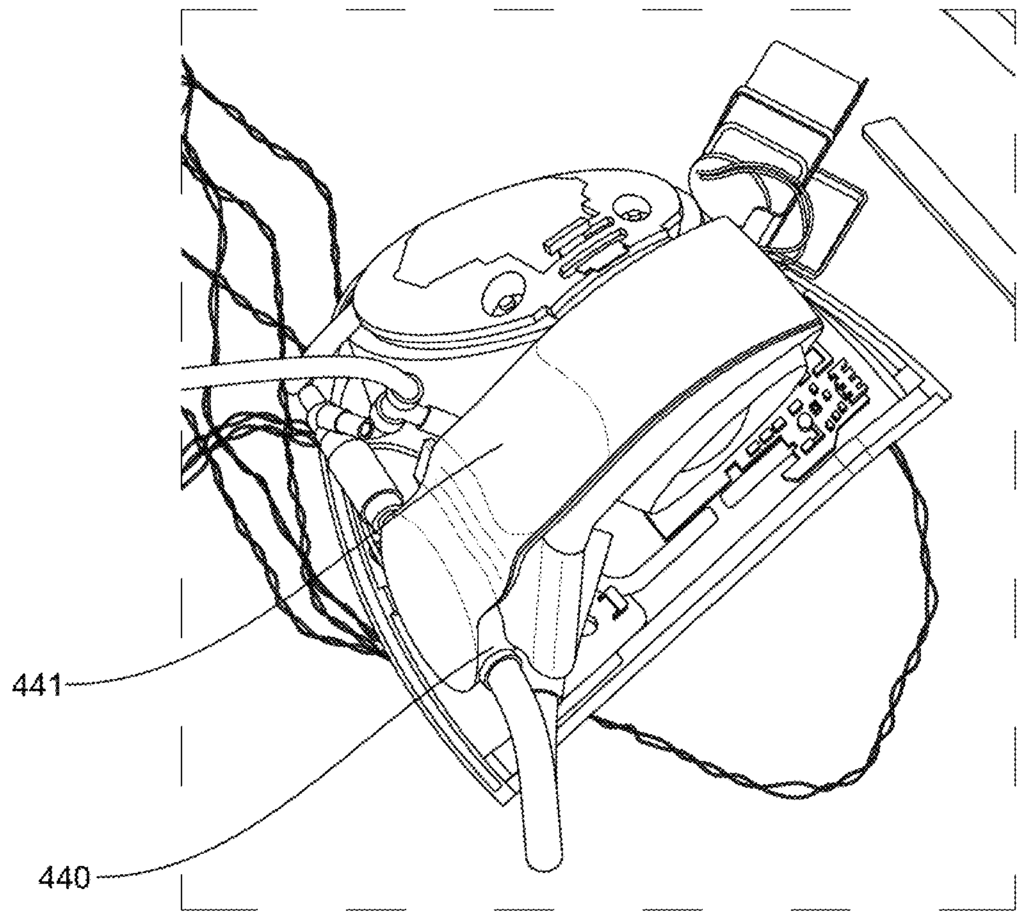

FIGURE 44

BREAST PUMP SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. application Ser. No. 17/181,057, filed on Feb. 22, 2021, which is a U.S. application Ser. No. 16/009,547, filed on Jun. 15, 2018, which is based on, and claims priority to, GB Application No. 1709561.3, filed Jun. 15, 2017; GB Application No. 1709564.7, filed on Jun. 15, 2017; GB Application No. 1709566.2, filed on Jun. 15, 2017; and GB Application No. 1809036.5, filed on Jun. 1, 2018, the entire contents of each of which being fully incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior Art Related to Breast Pump Systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also

require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult for a user to extract all of their milk from the bag, due to the small cut opening that is needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art Related to Liquid Measurement Systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk bottle is not always possible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US

2016/296681. In this apparatus, a sensing mechanism is provided at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art Related to Bra Clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in U.S. Pat. No. 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra; a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

FIG. **1** is a front view of an assembled breast pump system.

FIG. **2** is a rear view of the assembled breast pump system of FIG. **1**.

FIG. **3** is a front view of a partially disassembled breast pump system.

FIG. **4** is a rear view of the partially disassembled breast pump system of FIG. **3**.

FIG. **5** is a front view of a further partially disassembled breast pump system.

FIG. **6** is a rear view of the further partially disassembled breast pump system of FIG. **5**.

FIG. **7** is a front view of the breast pump system of FIG. **1**, with the outer shell translucent for ease of explanation.

FIG. **8** is a further front view of the breast pump system of FIG. **1**, with the front of the outer shell removed for ease of explanation.

FIG. **9** is a schematic view of a nipple tunnel for a breast shield.

FIG. **10** is a schematic of a pneumatic system for a breast pump system.

FIG. **11** is a schematic of an alternative pneumatic system for a breast pump system.

FIG. **12** is a schematic of a further alternative pneumatic system for a breast pump system.

FIG. **13** is a graph depicting measured pressure in the breast pump system of FIG. **12** over time.

FIG. **14** shows schematics for breast shield sizing and nipple alignment.

FIG. **15** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **16** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **17** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **18** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **19** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **20** shows a screenshot of an application running on a connected device.

FIG. **21** shows a screenshot of an application running on a connected device.

FIG. **22** shows a screenshot of an application running on a connected device.

FIG. **23** shows a screenshot of an application running on a connected device.

FIG. **24** shows a screenshot of an application running on a connected device.

FIG. **25** shows a screenshot of an application running on a connected device.

FIG. **26** shows a diagram of a breast pump sensor network,

FIG. **27** shows a sectional view of a device being used to determine the level of liquid in a container;

FIG. **28** shows a sectional view of the device and the container from FIG. **27** being used at a different orientation.

FIG. **29** shows a sectional view of the device and the container from FIG. **27** being used whilst undergoing acceleration.

FIG. **30** shows a sectional view of the device from FIG. **27** being used as part of a breast pump assembly.

FIG. **31** shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

FIG. **32** depicts a prior art design for a maternity bra;

FIG. **33** depicts a clip and clasp being fitted to a maternity bra.

FIG. **34** depicts an alternative clip for adjustment of a maternity bra.

FIG. **35** depicts the alternative clip of FIG. **34**.

FIG. **36** depicts an alternative clip for adjustment of a maternity bra.

FIG. **37** depicts an alternative clip for adjustment of a maternity bra.

FIG. **38** depicts an alternative clip for adjustment of a maternity bra.

FIG. **39** depicts adjustment of the maternity bra of FIG. **37**.

FIG. **40** shows a configuration with two piezo pumps mounted in series.

FIG. **41** shows a configuration of two piezo pumps mounted in parallel.

FIG. **42** shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

FIG. **43** shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

FIG. **44** shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System

Section B: An IR System

Section C: A Bra Clip

Section D: Piezo Pumps and Wearable Devices

Section A: The Elvie™ Breast Pump System

1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ ™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to FIG. **1** and FIG. **2**, the assembled breast pump system **100** includes a housing **1** shaped to substantially fit inside a bra. The housing **1** includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing **1**: the breast shield **7** and a milk container **3**. The breast shield **7** and the milk container **3** are directly removable or attachable from the housing **1** in normal use or during normal dis-assembly (most clearly shown in FIG. **5**). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield **7** or the milk container **3**. The breast shield **7** and milk container **3** may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing **1**, breast shield **7** that is holding a flexible diaphragm, and milk container **3** attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing **1**. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container **3**.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it self-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example, the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and dis-assembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of discrete parts.

The breast pump system **100** comprises a housing **1** and a milk collection container (or bottle) **3**. The housing **1** (including the one or more pumps and a battery) and the container **3** are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container **3** is attached to a lower face **1**A of the housing **1** and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump **100** may be arranged to be used with just the right or the left breast specifically, the breast pump **100** is preferably used with both breasts, without modification. To

this end, the outer surfaces of the breast pump **100** are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing **1** and milk container **3**) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system **100** gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focused on minimising the number of components.

The breast pump system **100** is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by FIG. **1**, is at around 60 mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40 mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85 mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60 mm below the centre of the nipple tunnel when the milk container is full. Generalising, the centre of gravity should be at least 2 mm below the centre of the nipple tunnel when the container is empty.

The breast pump **100** is further provided with a user interface **5**. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump **100**. Such functions might include turning the breast pump **100** on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface **5** might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing **1**.

In the particular embodiment of the Figures, the user interface **5** comprises power button **5**A for turning the pump on and off. The user interface **5** further comprises pump up button **5**B and pump down button **5**C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button **5**B could be physically larger than the pump down button **5**C. A play/pause button **5**D is provided for the user to interrupt the pumping process without turning the device off.

The user interface **5** further comprises a breast toggle button **5**E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a pair of LEDs, one to the left of the toggle button **5**E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button **5**E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button **5**E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in FIG. **1**, the housing **1** and milk collection container **3** form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump **100** to substantially fit within the cup of a user's bra. The milk collection container **3** is retained in attachment with the housing **1** by means of a latch system, which is released by a one-click release mechanism such as a push button **2** or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container **3** has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump **100** of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost point of the breast pump **100**, and the second of which is aligned with the outermost point of the breast pump **100**. This distance is preferably less than 100 mm.

FIG. **2** is a rear view of the breast pump **100** of FIG. **1**. The inner surface of the housing **1** and milk collection container **3** are shown, along with a breast shield **7**. The housing **1**, milk collection container **3** and breast shield **7** form the three major subcomponents of the breast pump system **100**. In use, these sub-components clip together to provide the functioning breast pump system **100**. The breast shield **7** is designed to engage with the user's breast, and comprises a concave inner flange **7**A which contacts the breast. To allow the breast pump **100** to be used on either of the user's breasts, the breast shield **7** is preferably substantially symmetrical on its inner flange **7**A.

The inner flange **7**A is substantially oval-shaped. While the inner flange **7**A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange **7**A and the outermost point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange **7**A of the breast shield **7** may extend over the majority of the inner surface of the housing **1** and milk collection container **3**. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield **7** substantially aligns with the outer edge **1**B of the housing **1**. The milk collection container **3** may be provided with an arcuate groove for receiving a lower part of the breast shield **7**. This is best shown in later Figures. In the assembled arrangement of FIGS. **1** and **2**, the inner surface of the breast pump **100** is substantially continuous.

The breast shield **7** comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel **9**) aligned with the opening and extending away from the user's breast. Breast shield nipple tunnel **9** extends from a curved section **7**B in the breast shield **7**. In preferable embodiments the nipple tunnel **9** is integral with the breast shield **7**. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section **7**B is positioned over the user's nipple and areola in use. The breast shield **7** forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel **9** defines a milk-flow path from the inner surface of the breast shield **7**A, through the breast shield nipple tunnel **9** and into the milk collection container **3**. The breast shield nipple tunnel **9** is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel **9** may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel **9** is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening **9**A for depositing milk into the collection container and a second opening **19**A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange **7**A and nipple tunnel **9** may be detachable from the housing **1** together. The shield flange **7**A and nipple tunnel **9** being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel **9** will be integral with the breast shield **7**, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

FIGS. **3** and **4** are of a partially disassembled breast pump **100** of the present invention. In these Figures, the breast shield **7** has been disengaged from the housing **1** and milk collection bottle **3**. As shown in FIG. **4**, the housing **1** comprises a region or slot **11** for receiving the breast shield nipple tunnel **9** of the breast shield **7**. The breast shield is held in place thanks to a pair of channels (**9**B) included in the nipple tunnel **9**, each channel including a small indent. When pushing the housing **1** onto the breast shield **7**, which has been placed over the breast, ridges in the housing (**9**C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each ridge facilitates movement of the housing on to the nipple tunnel **9**. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield **7** onto her breast and with her other hand, position and secure the housing **1** on to the breast shield **7**. The breast shield **7** can be readily separated from the housing **1** since the ball bearing latch only lightly secures the breast shield **7** to the housing **1**.

Alternatively, the breast shield **7** may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield **7**, with the slot in a corresponding location.

The breast shield nipple tunnel **9** of the breast shield **7** is provided with an opening **9**A on its lower surface through which expressed milk flows. This opening **9**A is configured to engage with the milk collection bottle **3**.

The breast pump **100** further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm **13** seated into diaphragm housing **19**A.

The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing **19**A includes a small air hole into the nipple tunnel **9** to transfer negative air pressure into nipple tunnel **9** and hence to impose a sucking action on the nipple placed in the nipple tunnel **9**.

Hence, the air pump acts on one side of the barrier or diaphragm **13** to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing **19**A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing **19**A. The milk-flow path extending under the outer periphery or surface of the barrier **19**A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier **13** or surface of diaphragm housing **19**A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier **32**. This results in a simpler and smaller barrier design.

As noted, the diaphragm **13** is mounted on diaphragm housing **19**A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier **13** may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier **13**. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in FIGS. **3** and **4**, the barrier may include a flexible diaphragm **13** formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm **13** is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm **13**. This means that the milk-flow pathway does not extend through the diaphragm **13**. In particular, the milk-flow pathway is beneath the diaphragm **13**. However, the diaphragm **13** may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm **13**.

Preferably, the diaphragm **13** is a continuous membrane, devoid of any openings. The diaphragm **13** is held in a diaphragm housing **19**, which is formed in two parts. The first half **19**A of the diaphragm housing **19** is provided on the outer surface of the breast shield **7**, above the breast shield nipple tunnel **9** and hence the milk-flow pathway. In preferred embodiments, the first half **19**A of the diaphragm housing **19** is integral with the breast shield. The second half **19**B of the diaphragm housing is provided in a recessed portion of the housing **1**. The diaphragm **13** self-seals in this diaphragm housing **19** around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm **13** is the only seal of the diaphragm **13**. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well.

Having the diaphragm **13** mounted in the breast pump **100** in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield **7** and diaphragm **13** are the only components which need to be removed from the pump **100** for cleaning. Because the diaphragm **13** self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

FIGS. **5** and **6** show a breast pump **100** according to the present invention in a further disassembled state. In addition to the breast shield **7** and diaphragm **13** being removed, the milk collection container **3** has been unclipped. Preferably, the milk collection container **3** is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container **3** may be formed of three sections: a front bottle portion, a rear bottle portion, and a cap. These three sections may clip together to form the milk collection container **3**. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout **35** or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve **37** (or 'sealing plate seal') is mounted onto the cap or spout **35** and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve **37** self-seals against opening **9**A in nipple tunnel **9**. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system **100** is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container **3** has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container **3** preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container **3** further preferably has a height, extending in the direction from the bottom of the container **3** in use to the cap or spout or sealing plate **35**, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap **35** may screw into the milk collection bottle **3**. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container **3** in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap **35** is provided with a one-way valve **37**, through which milk can flow only into the bottle. This valve **37** prevents milk from spilling from the bottle once it has been collected. In addition, the valve **37** automatically seals completely unless engaged to the breast shield **7**. This ensures that when the pump **100** is dismantled immediately after pumping, no milk is lost from the collection bottle **3**. It can be appreciated that this one-way valve **37** might also be placed on the breast shield **7** rather than in this bottle cap **35**.

Alternatively, the milk bottle **3** may form a single integral part with a cap **35**. Cap **35** may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion **31**A or attach to the spout that is integral with cap **35**, to allow the container **3** to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion **31**A for ease of pouring. A cap may also be provided to attach to the protrusion **31**A in order to seal the milk collection bottle **3** for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement markings (**3**A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was

filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

FIGS. **7** and **8** show front views of a breast pump system **100**. The outer-surface of the housing **1** has been drawn translucent to show the components inside. The control circuitry **71** for the breast pump **100** is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container **3**. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button **5**E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry **71** for charging the battery **81**. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port **6** is shown for charging the battery **81**. This port **6** may be located anywhere appropriate on the housing **1**.

FIG. **8** shows the location of the battery **81** and the pumps **83**A, **83**B mounted in series inside the housing **1**. While the depicted embodiment shows two pumps **83**A, **83**B it is appreciated that the present invention may have a single pump. Preferably, an air filter **86** is provided at the output to the pumps **83**A, **83**B. In preferable embodiments, the pumps **83**A, **83**B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing **19**B in the housing **1** is provided with a pneumatic connection spout. The pumps **83**A, **83**B are pneumatically connected with this connection spout.

Operation of the breast pump **100** will now be described. Once the breast pump **100** is activated and a pumping cycle is begun, the pumps **83**A, **83**B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm **13** mounted on the diaphragm housing **19**A. This side of the diaphragm **13** is denoted the pumping side **13**B of the diaphragm **13**.

The diaphragm **13** transmits this negative air pressure to its opposite side (denoted the milk-flow side **13**A). This negative pressure is transferred through a small opening in the diaphragm housing **19**A to the breast shield nipple tunnel **9** and the curved opening **7**B of the breast shield **7** that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel **9**, to the one way valve **37** that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve **37** opens and milk flows under gravity past the valve **37** and into milk container **3**. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump **100** is provided with two pumps, the following schematics will be described with a single pump **83**. It is understood that the single pump **83** could be replaced by two separate piezo air-pumps **83**A, **83**B as above.

FIG. **9** depicts a schematic of a further embodiment of a breast shield nipple tunnel **9** for a breast pump **100**. The breast shield nipple tunnel **9** is provided with an antechamber **91** and a separation chamber **93**. A protrusion **95** extends from the walls of the breast shield nipple tunnel **9** to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel **9**. In the separation chamber **93** there are two opening **97**, **99**. An air opening **97** is provided in an upper surface **93**A of the separation chamber **93**. This upper surface **93** is provided transverse to the direction of the breast shield nipple tunnel **9**. This opening **97** connects to the first side of the diaphragm housing **19**A and is the source of the negative pressure. This airflow opening **97** also provides a route for air to flow as shown with arrow **96**. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel **9** without such a pathway will work.

The other opening **99** is a milk opening **99**. The milk opening **99** is provided on a lower surface **93**B of the separation chamber **93** and connects in use to the container **3**. After flowing through the tortuous breast shield nipple tunnel **9** pathway, the milk is encouraged to flow through this opening **99** into the container **3**. This is further aided by the transverse nature of the upper surface **93**A. In this manner, expressed milk is kept away from the diaphragm **13**. As such, the breast pump **100** can be separated into a "air" side comprising the pump **83**, the connection spout **85** and the pumping side **13**B of the diaphragm **13** and a "milk-flow" side comprising the breast shield **7**, the milk collection container **3** and the milk-flow side **13**A of the diaphragm **13**. This ensures that all of the "milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump **83**, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm **13**, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

FIG. **10** shows a schematic of a basic pneumatic system **200** for a breast pump **100**. In the system **200** milk expressed into the breast shield **7** is directed through the breast shield nipple tunnel **9** through the torturous air-liquid labyrinth interface **95**. The milk is directed through the non-return valve **37** to the collection container **3**. This side of the system forms the "milk-flow" side **201**.

The rest of the pneumatic system **200** forms the air side **202** and is separated from contact with milk. This is achieved by way of a flexible diaphragm **13** which forms a seal between the two sides of the system. The diaphragm **13** has a milk-flow side **13**A and an air side or pumping side **13**B.

The air side **202** of the system **200** is a closed system. This air side **202** may contain a pressure sensor **101** in pneumatic connection with the diaphragm **13** and the pump **83**. Preferably, the pump **83** is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump **83** has an output **83**A for generating pressure, and an exhaust to the atmosphere **83**B. In a first phase of the expression cycle, the pump **83** gradually applies negative pressure to half of the closed system **202** behind the diaphragm **13**. This causes the diaphragm **13** to extend away from the breast, and thus the diaphragm **13** conveys a decrease in pressure into the breast shield **7**. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system **95** and the one-way valve **37** to the collection bottle **3**.

While in the depicted embodiment the air exhaust **83**B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side **202** further comprises a two-way solenoid valve **103** connected to a filtered air inlet **105** and the pump **83**. Alternatively, the filter could be fitted on the pump line **83**A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system **202** through the valve **103** in a second phase of the expression cycle. In this embodiment, the air filter **105** is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve **103** is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor **101**.

In certain embodiments, if the elasticity and extension of the diaphragm **13** may be approximated mathematically at different pressures, the pressure measured by sensor **101** can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm **13**. FIG. **11** shows an alternative pneumatic system **300**. The core architecture of this system is the same as the system shown in FIG. **10**.

In this system **300**, the closed loop **202** is restricted with an additional three way solenoid valve **111**. This valve **111** allows the diaphragm **13** to be selectively isolated from the rest of the closed loop **202**. This additional three way valve **111** is located between the diaphragm **13** and the pump **83**. The pressure sensor **101** is on the pump **83** side of the three way valve **111**. The three way valve **111** is a single pole double throw (SPDT) valve, wherein: the pole **111**A is in pneumatic connection with the pump **83** and pressure sensor; one of the throws **11** is in pneumatic connection with the diaphragm **13**; and the other throw **111**C is in pneumatic connection with a dead-end **113**. This dead-end **113** may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system **202**. This could include, for example, an arrangement of one-way valves.

In this system **300**, therefore, the pump **83** has the option of applying negative pressure directly to the pressure sensor **101**. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump **83** to the dead end **113**. The pump **83** then pulls directly against the dead end **113** and the reduction of pressure within the system can be detected by the pressure sensor **101**.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user-indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the

pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

FIG. **12** shows a schematic for a system **400** for a breast pump **100** which can estimate the volume of milk collected in the collection container **3** from data collected on the air-side part **202** of the system **400**.

The pump **83** is connected to the circuit via two bleed valves **126**, **128**. The first bleed valve **126** is arranged to function when the pump **83** applies a negative pressure. As such, this valve **126** is connected to a "bleed in" **127**, for supplying atmospheric air to the system **202**.

The second bleed valve **128** is arranged to function when the pump **83** applies a positive pressure. As such, this valve **128** is connected to a "bleed out" **129** for bleeding air in the system **202** to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump **83** applies negative pressure on the air side **13**B of the diaphragm **13** which causes its extension towards the pump **83**. This increases the volume of the space on the milk side **13**B of the diaphragm **13**. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves **121**, **123**, **125** ensure that this decrease in pressure is applied only to the breast (via the breast shield **7**) and not the milk collection container **3**. To measure the volume of milk collected in the container **3**, the pump **83** is used instead to apply positive pressure to the diaphragm **13**. The diaphragm **13** is forced to extend away from the pump **83** and conveys the pressure increase to the milk side **201** of the system **400**. The three non-return valves **121**, **123**, **125** ensure that this increase in pressure is exclusively conveyed to the milk collection container **13**.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm **13** from the air-side **202** by a pressure sensor **101**. Preferably, the pressure sensor **101** is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump **83** (at constant strength) is able to increase the pressure in the system **400** is a function of the volume of air that remains in the milk collection container **3**. As air is many times more compressible than liquid, the rate at which pressure increases in the system **400** can be expressed as an approximate function of the volume of milk held in the collection container **3**.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container **3** is calculable. FIG. **13** shows repeated milking and volume measurement cycles as the collection container **3** is filled. To determine the rate of pressure increase the pump **83** was run for a fixed time. As pumping proceeds and the volume of air reduces in the system **400**, the pump **83** is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike **41**. There is a clear upwards trend **43** in magnitude of positive pressures achieved as the collection container **3** is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container **3** based upon the measured pressures.

FIG. **13** also shows a dead end stop pump test **45** as described above. The negative spike shows the application of negative pressure directly to the pressure sensor **101**.

2. Breast Shield Sizing and Nipple Alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to FIG. **14**, three breast shield sizes are shown (A**1**, B**1**, C**1**). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A**2**, B**2**, C**2**). The transparent breast shield allows the user to observe the nipple while adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct alignment is illustrated B**2**.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the

rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

FIGS. **15** to **20** show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

FIG. **15** shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

FIG. **16** shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

FIG. **17** shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (−) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

FIG. **18** shows a page providing a summary of the last recorded pumping session.

FIG. **19** shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. FIG. **20** shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

FIG. **21** shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre-program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in FIG. **22**.

FIG. **23** shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to FIG. **24**, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to FIG. **25**, a page summarising the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast Pump Data Analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

FIG. **26** illustrates an outline of a smart breast pump system network which includes the breast pump system (**100**) in communication with a peripheral mobile device and application (**270**) and several cloud-based databases (**268**, **273**). The breast pump system (**100**) includes several sensors (**262**). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve(s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (**263**). In addition, any interactions, and data from these components, may be stored in memory (**264**).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (**265**) which can be used to communicate wirelessly with connected

devices such as a peripheral mobile device (**270**). Through this connection any sensor data (**267**) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (**273**). In addition, the communication chip will also allow the sending of user control data/firmware updates from the connected device to the breast pump system (**266**).

Raw data (**271**) collected from the measurement sub-system including sensors (**262**) may be analysed on a cloud database and the analysed data may be stored on the cloud (**272**). Through inferences provided by the analysed data, firmware updates (**269**) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (**268**).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (**264**) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

- the quantity of the liquid in the container above its base;
- the height of the liquid in the container above its base;
- the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

- an estimation of the flow rate;
- an estimation of the fill rate;
- an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or title angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

- indicate whether the milk is flowing or not flowing,
- measure or infer the quantity and/or height of the liquid in the container above its base,
- give recommendations to the mother for optimal metrics for optimal milk flow,
- give recommendations to the mother for optimal metrics for weaning,
- give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),
- give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,
- automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.
- automatically stop pumping when the milk container is full,
- automatically adjust one or more pumping parameters to achieve an optimum pumping session,
- automatically adjust one or more pumping parameters to achieve a comfortable pumping session,
- automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or

any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymised and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

Section B: IR System

This section describes the milk detecting system used in the Elvie™ pump.

With reference to FIGS. **27** and **28**, there is shown a device **270** for use in detecting the level of liquid inside a container **275**. The device **270** is formed of a housing **271** in which is located a sensing assembly **272** comprising a series of optical emitters **273** (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver **274**. In operation of the device as will be described, each optical emitter **273** is operable to emit radiation which is received by the optical receiver **274**. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver **274**.

The optical emitters **273** and the optical receiver **274** from the sensing assembly **272** are located in a portion **276** of the device **270** which faces the container **275** when the device is connected to the container **275**. The portion **276** of the device **270** containing the optical emitters **273** and the optical receiver **274** comprises a window **277** of material which is transparent to optical radiation. In this way, each of the optical emitters **273** and the optical receiver **274** have a line of sight through the window **277** into the container **275** when the device **270** is connected thereto.

A controller **278** comprising a CPU **279** and a memory **280** is provided in the device **270** for controlling the operation of the sensing assembly **272**. An accelerometer **281** is also provided in the housing **271**, which is operatively connected to the controller **278**. Operation of the device **270** when connected to the container **275** will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container **275**, the controller **278** instructs the optical emitters **273** to each emit radiation towards the surface of the liquid inside the container **275** at a given intensity. The optical receiver **274** receives the reflected radiation from each optical emitter **273** via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly **272**, the controller **278** records the intensities of radiation emitted by each of the optical emitters **273** as intensities IE**1**; IE**2** . . . IEn (where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver **274** from each of the optical emitters **273** as received intensities IR**1**; IR**2** . . . IRn.

By comparing the emitted radiation intensities IE**1**; IE**2** . . . IEn with the received radiation intensities IR**1**; IR**2** . . . IRn, the controller **278** calculates a series of intensity ratios IE**1**:IR**1**; IE**2**:IR**2** . . . IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE**1**:IR**1** is the same as IE**2**:IR**2**, given the optical emitters **273** are equidistant from the optical receiver **274**, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in FIG. **27**. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in FIG. **28**.

To accurately determine the level and the quantity of liquid inside the container **275**, the controller **278** processes the recorded intensity ratios using a database located in the memory **280**. The database contains an individual record for each container which is operable to connect with the device **270**. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE**1**:IR**1** and IE**2**:IR**2**) for the container **275** when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller **278** calculates the level and quantity of liquid inside the container **275** and stores this information in the memory **280**.

In situations where a container **275** to the device **270** contains no stored record in the database, the sensing assembly **272** can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly **272** is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller **278** calculates the recorded intensity ratios (IE**1**:IR**1** and IE**2**:IR**2**) and stores them in the record relating to the container **275**. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container **275**.

To improve the accuracy of the results obtained by the device **270** during its use, the controller **278** when recording each intensity ratio also records a parameter from the accelerometer **281** relating to the acceleration experienced by the device **270**. For each recorded acceleration parameter, the controller **278** determines whether the parameter **278** exceeds a predetermined threshold acceleration parameter stored in the memory **280**. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container **275** connected to the device **270**. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller **278** flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer **281**, the controller **278** is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller **278** checks whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller **278** determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in FIG. **29**. In this event, the controller **278** flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters **273**

with the radiation received by the optical emitter **274**, the controller **278** could instead record the time taken for radiation emitted by each of the optical emitters **273** to be received by the optical receiver **274**. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device **270**, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device **270** to determine the level of liquid located within a container **275**, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device **270** is associated with a breast pump **301** which assists with the expression of milk from a breast. The breast pump may be located in the housing **271** of the device **270** as shown in FIG. **30**, or it may be realisably connected to the housing **271**.

Either way, the device **270** would be connectable to the container **275** such that milk expressed by the breast pump can pass from the pump via a channel **302** into the container **275**.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible—further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10 nm and 1 mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device **270** is as a collar for detecting the level/quantity of liquid in a container **275**, such as a baby bottle, via its lid **310**. An example of the device **270** being used as such a collar is shown in FIG. **31**. In this arrangement, the device **270** is located between the container **275** and the lid **310**, and comprises a first end **311** having a first coupling **312** for attaching the collar to the lid **310**. The device comprises a second end **313** having a second coupling **314** for attaching the device **270** to the container **275**. The second coupling may be a screw thread, shown in FIG. **31**, on the inside surface of the container **275**. In this way, the distinctive bottom inside surface can be used by the sensing assembly **272** to more easily calibrate itself to the container **275** on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container **275** the device is connected to, and thus which record should be used from the database when the device **270** is used.

To further improve the accuracy of the sensing assembly **272**, the controller **278** may also be configured to use the recorded information from the accelerometer **281**, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller **278** may poll the accelerometer **281** prior to each operation of the sensing assembly **272** to verify that the device **270** is not currently undergoing excessive acceleration. In the event of the controller **278** determining excessive acceleration in the device **270**, the controller **278** would continually re-poll the accelerometer, and not operate the sensing assembly **272**, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory **280**.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity ratios. In this way, the device **270** can more accurately determine the level/quantity of different liquids used in a particular container **275**.

As described herein, the sensing assembly **272** has been described as having a plurality of optical emitters **273**. It will be appreciated however that the sensing assembly could operate using a single optical emitter **273** and plurality of optical receivers **274**. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter **273** as received by each of the optical receivers **274**. In use of the device **270**, the controller **278** would then similarly record

the emitted radiation from the optical emitter **273** as received by each of the optical receivers **274**. In an alternate arrangement, there may be provided a plurality of optical emitters **273** and a plurality of optical receivers **274**, wherein each optical emitter **273** is associated with a respective optical receiver **274**. In its simplest arrangement, the sensing assembly **272** may comprise a single optical emitter **273** and a single optical receiver **274**.

In certain configurations, the optical emitters **273** may together emit radiation having the same wavelength. In other configurations, the optical emitters **273** may each emit radiation having a different wavelength. In this latter configuration, the optical receiver **274** would then be able to determine which optical emitter **273** is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters **273** may also each emit radiation at different times, such to allow the controller **278** to more easily process the signals from the optical receiver **274**, and more easily distinguish between the radiation emitted by each of the optical emitters **273**.

In relation to the electrical connection between the controller **278** and the sensing assembly **272**, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device **270** herein described is preferably powered by a battery or some other power source located in the device **270**. In other embodiments, the device **270** may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller **278** comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container **275**, the controller **278** could instead process the recorded intensity ratios through a liquid-level equation stored in the memory **280**. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device **270**, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400 nm-700 nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700 nm-1 mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10 nm to 400 nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

Section C: Bra Clip

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in FIG. **32**, a typical maternity bra **320** comprises a support structure made up of shoulder straps **321** which support the bra **320** on the wearer's shoulders, and a bra band **322** for extending around a user's ribcage, comprising two wings **323** and a central panel or bridge **324**. The straps **321** are typically provided with adjustment mechanisms **325** for varying the length of the straps **321** to fit the bra **320** to the wearer. At the outermost end of each wing, an attachment region **326** is provided. Typically, hooks **327** and loops **328** are provided for securing the bra **320** at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region **326** may be provided at the front of the bra **320** in the bridge region **324**, with a continuous wing **323** extending continuously around the wearer's back. Typically, a number of sets of loops **328** are provided to allow for variation in the tightness of the bra **320** on the wearer. While shown as having a separation in FIG. **32**, the wings **323** and bridge **324** may form a single continuous piece in certain designs. Likewise, while shown with a distinct separation in FIG. **32**, the shoulder straps **321** and the wings **323** may likewise form a single continuous piece.

The maternity bra **320** is further provided with two breast-supporting cups **329** attached to the support structure. The cups **329** define a cup size, which defines the difference in protrusion of the cups **329** from the band **322**. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups **329** from the band **322**. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc.

The cups **329** may be stitched to the bra band **321**. At least one of the cups **329**, is in detachable attachment with the corresponding strap **321**. In particular, this is achieved at attachment point **330** where a hook **331** attached to the bra strap **321** engages with a clasp **331** attached to the cup **329**. The hook **331** and the bra strap adjuster **325** are set such that in the closed position, the cup size of the bra **320** fits the wearer's breasts.

In FIG. **32**, the left cup **329** is shown attached to its attachment point **330**, which the right cup **329** is unattached. In this manner, the wearer is able to detach the cup **329** to expose their breast for feeding or for breast pumping. Once this is completed, the cup **329** is reattached and the maternity bra **320** continues to function as a normal bra.

While in the depicted embodiments, a hook **331** is shown on the bra strap **321** and a clasp **332** is shown on the cup **329**, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point **330** may be provided at a different location, such as at the attachment between the bra band **322** and the cup **329**. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

FIG. **33** depict a clip **335** according to the present invention, along with a clasp **332** shown in isolation from the bra cup **329** it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip **335** is provided with a material pathway **336** which receives a portion of the bra strap **321**. In the particular embodiment of these Figures, the clip **335** is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip **335** is designed to be attached to the bra strap **321** in a releasable manner, with the slot **336** acting as a support engaging mechanism. The releasable manner means that the clip **335** may be simply removed from the bra **320** without causing any damage to the functioning of the bra **320**. To enhance the ease of attachment, the clip **335** may be provided with outwardly extending wings **204** which help direct the bra strap **321** into the clip **335**. The clip **335** is further provided with a hook **220** acting as a cup engaging mechanism which can engage with the clasp **332**.

FIG. **33** (*c*) shows the clip **335** being attached to a bra strap **321** in order to provide a second attachment point **337** for the clasp **332** to attach to, and hence to provide a second cup size for the bra **320**. In this particular embodiment, the clip **335** is attached in a portion of strap **321**A below the original attachment point **330** and hence the second attachment point **337** is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip **335** engages with the support structure in a direction transverse to the direction in which it engages with the cup.

FIGS. **33** (*d*) and (*e*) show how a wearer is able to move between the first and second cup sizes. In **33**(*d*), the cup **329** is attached at the first attachment point **330** to provide a first cup size. The wearer then disengages the clasp **332** from the hook **331** at the hook **338** at the second engagement point **239**. In this manner, the wearer is easily able to transition between the two cup sizes.

FIGS. **34** and **35** show an alternative design for a clip **340**. This clip **340** is substantially "E-shaped", with a back portion **341** and first, second and 5 third prongs **342**A, **342**B, **342**C extending transverse from this back portion **341**. The three prongs **342**A, **342**B, **342**C are spaced apart along the length of the back portion **341**. The first and third prongs **342**A, **342**C are provided with attachment clips **343**A, **343**B.

These attachment clips **343**A, **343**B can engage with the clasp **332** of a bra to provide the second cup size. Depending upon the orientation of the clip **300**, one or the other of the attachment clips **343**A, **343**B will be used to attach the clasp **332** of the bra. By providing these clips **343**A, **343**B on both of the first and the third prongs **342**A, **342**C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip **340** is also symmetrical, to aid the reversibility of the clip **340**.

FIG. **35** shows the clip **340** attached to a bra. As can be seen, the first and third prongs **342**A, **342**C extend on the front side of the bra strap, with the second prong **342**B extending on the rear side of the bra strap. In this manner, the clip **340** is attached to the strap. In preferable embodiments, a grip-enhancing member **344** such as a number of projections and/or roughened patches can be provided on the second prong **342**B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong **342**B. In such an arrangement, the centremost prong **342**B would be on the outside of the bra, with the first and third prongs **342**A, **342**C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point **330** when the breast pump device is not being used. As shown in FIG. **33**, the clasp **332** is then engaged by the user to discretely

switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip **360** as shown in FIG. **36**. In such an embodiment the clip is attached to the hook **331** on the strap **321** in a releasable manner, with the clasp **332** attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp **332** is held in substantially the same position as the first attachment point **330** to provide the first cup size, and an expanded state, where the clasp **332** is held in a second position away from the first attachment point **330** to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook **331** is provided at the first end, and a second attachment point for attaching to the clasp **332** is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp **332** is held in substantially the same location as the first attachment point **330** to provide the first cup size, and in the open position the clasp is held away from the first attachment point **330** to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in FIGS. **37** and **38**. The alternative proposed solution is a small adapter device, which comprises a first portion **370** including a clasp **373** and a second portion **372** including a hook **374**, in which the first and second portions are separated by a small distance **371** in order to provide two different adjustable sizes. The first portion includes a clasp **373** that is designed to attach to the hook on the bra strap **321**. It may also include a top hook **375** positioned underneath the clasp, and a clip **376** on the rear side. The second portion includes a bottom hook **372**.

The clasp **332** that is present on the cup **329** of the maternity bra, may then either engage with the top hook (**321**) to provide a first cup size, and engage with the bottom hook (**332**) to provide a second cup size that is different from the first cup size, as illustrated in FIG. **39**. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (**100**).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter.

Each individual Piezo pump weighs approximately 6 gm and may, with material and design improvements, weigh less than 6 gm.

In operation, the Elvie breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise; tests indicate that it makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of FIGS. **7** and **8**, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to FIG. **40**, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to FIG. **41**, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to FIG. **42**, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In this example, the parallel configuration produces higher flow rate and achieves −100 mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100 mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at −140 mmHg. In comparison, the series configuration is able to generate about −240 mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

FIG. **43** shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500 ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48° C. and preferably no more than 43° C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

FIG. **44** shows a picture of a wearable breast pump housing including multiple piezo pumps (**440**). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore connected to a heat sink (**441**), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

Wound therapy;

High degree burns;

Sleep apnea;

Deep vein thrombosis;

Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. Elvie Breast Pump: General Usability Feature Cluster

B. Elvie Piezo Air Pump Feature Cluster

C. Elvie Milk Container Feature Cluster

D. Elvie IR System Feature Cluster

E. Elvie Bra Clip Feature Cluster

F. Other Features, outside the breast pump context

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm

Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1-42 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is Wearable and Includes Only Two Parts that are Removable from the Pump Main Housing in Normal Use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.

Milk only flows through the breast shield and then directly into the milk container.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

- Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- No other parts are removable from the breast shield, apart from the flexible diaphragm.
- The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.
- No other parts are removable from the milk container, apart from the cap and the valve.
- All parts that are user-removable in normal use are attached to either the breast shield or the milk container.
- Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is Wearable and Includes a Clear Breast Shield Giving an Unobstructed View of the Breast for Easy Nipple Alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.
- The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.
- Entire breast shield is substantially transparent.

- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.
- Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.
- Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.
- Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.
- Breast shield latches into position against the housing.
- Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.
- Breast shield latches into position against the housing using magnets.
- Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.
- Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.
- Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.
- Nipple tunnel includes on its lower surface an opening through which expressed milk flows.
- Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.
- A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.
- The milk container mechanically or magnetically latches to the housing.
- The milk container is released by the user pressing a button on the housing.
- The milk container includes a removable cap and a removable valve that is seated on the lid.
- In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is Wearable and Includes a Clear Breast Shield with Nipple Guides for Easy Breast Shield Sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

- The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.
- Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.
- Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is Wearable and Includes a Breast Shield that Audibly Attaches to the Housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is Wearable and Includes a Breast Shield that Attaches to the Housing with a Single Push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

The single push action overcomes a latching resistance.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

The milk container mechanically or magnetically latches to the housing.

The milk container is released by the user pressing a button on the housing.

The milk container includes a removable cap and a removable valve that is seated on the lid.

In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is Wearable and not Top Heavy, to Ensure Comfort and Reliable Suction Against the Breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.

In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.

System is configured so that its centre of gravity is no more than 60 mm up from the base of the milk container also below the top of the user's bra cup.

In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.

In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is Wearable and has a Night Mode for Convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Control system is implemented in hardware in the pump itself using a 'night mode' button.

Control system is implemented in software within a connected device app running on the user's smartphone.

Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is Wearable and Includes a Haptic or Visual Indicator Showing when Milk is Flowing or not Flowing Well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase

The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The haptic and/or visual indicator provides an indication of an estimation of the flow rate.

The visual indicator provides a colour-coded indication of an estimation of the flow rate.

The visual indicator provides an indication of how much of the container has been filled.

The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.

The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.

A sub-system measures or infers the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.

A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.

Milk container is attached to the lower part of the housing and forms the base of the breast pump system.

Milk container is made of transparent material.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 Elvie is Wearable and Collects Data to Enable the Mother to Understand What Variables (e.g. Time of Day, Pump Speed Etc.) Correlate to Good Milk-Flow

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

User-defined requirement is to enhance or increase milk-flow.

User-defined requirement is to reduce milk-flow.

The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.

The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.

measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.

Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Data analysis system gives recommended metrics for improving milk flow

Data analysis system gives recommended metrics for weaning.

Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).

Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.

Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.

Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).

The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.

The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is Wearable and Collects Data that can be Exported to Social Media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.

The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.

The social media or community function or platform organizes the collected data into different profiles.

The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.

each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.

Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

The application is connected to other applications residing on the connected device, such as a fitness app.

The collected data includes data received from other connected apps.

The collected data is anonymised before it is shared.

The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.

The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is Wearable and has a Smart Bottle that Stores the Time and/or Date of Pumping to Ensure the Milk is Used when Fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Memory or tag is programmed to store the quantity of milk in the milk container.

Memory or tag stores the milk expiry date.

Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.

System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.

Clock is in the housing.

Clock is in the milk container.

Milk container includes a display that shows the time and/or date it was filled with milk.

Milk container includes a display that shows the quantity of milk that it was last filled with milk.

Milk container includes a display that shows whether the left or right breast was used to fill the milk container.

Memory or tag is connected to a data communications sub-system.

Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.

Reader device shows the time and/or date a specific milk container was filled with milk.

Reader device shows the quantity of milk that a specific milk container was last filled with.

Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.

Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.

A sub-system measures or infers milk flow into the milk container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

The sub-system is in the housing.

Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 a Smart Bottle that Stores the Time and/or Date of Pumping to Ensure the Milk is Used when Fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date

and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

The container includes wireless connectivity and connects to a companion app.

The memory or tag includes an NFC chip and is read using a NFC reader.

The memory or tag stores also an expiry date.

Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.

The memory or tag stores also the quantity of milk stored.

System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.

Clock is in the housing.

Clock is in the container.

Milk container includes a display that shows the time and/or date it was filled with milk.

Milk container includes a display that shows the quantity of milk that it was last filled with milk.

Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.

Milk container includes a display that shows the expiry date.

memory or tag is connected to a data communications sub-system.

Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.

Reader device shows the time and/or date a specific milk container was filled with milk.

Reader device shows the quantity of milk that a specific milk container was last filled with.

Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.

Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.

Reader device shows the expiry date.

Container includes wireless connectivity and connects to a companion application.

An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.

The pump is wearable.

The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.

Container is used for liquids other than milk.

Feature 13 Elvie is Wearable and Includes a Sensor to Infer the Amount of Movement or Tilt Angle During Normal Use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.

If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.

When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.

If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.

The container includes an optically clear region.

There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.

The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.

If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.

The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.

The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.

System includes a breast shield that attaches to the housing.

System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie Includes a Control to Toggle Between Recording Whether Milk is being Expressed from the Left Breast and the Right Breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

Control interface is a physical interface on the housing.

Control interface is a single button on the housing.

Control interface is from an application running on a device, such as a smartphone or smart ring.

Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.

The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.

The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.

Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie Includes a Pressure Sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements

The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.

The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.

The air pressure sensor detects pressure created by the pumping mechanism.

Sensor is a piezo air pressure sensor

Air pressure sensor measures the negative air pressure during a normal milk expression session.

Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.

Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance

Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.

The operation of the pumping mechanism is varied by altering the duty or pump cycle.

The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie Includes a Microcontroller to Enable Fine Tuning Between Pre-Set Pressure Profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

The user manually varies the pressure using a control interface on a housing of the breast pump system

The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.

The user manually varies the pressure by altering a control parameter of the pumping mechanism.

The user manually varies the pressure by altering the duty cycle or timing of the pumping mechanism.

The user manually varies the pressure by altering the voltage applied to the pumping mechanism.

The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Pressure profile defines one or more maximum negative air pressure levels.

Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.

Pressure profile defines one or more cycle time.

Pressure profile defines peak flow rate.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie Enables a User to Set the Comfort Level they are Experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system

The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.

The system stores user-indicated comfort levels together with associated parameters of the pumping system.

The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.

The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.

System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.

System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie Includes a Microcontroller to Dynamically and Automatically Alter Pump Operational Parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.

The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.

The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.

The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.

The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.

Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.

System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie Automatically Learns the Optimal Conditions for Let-Down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.

The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.

The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold or are otherwise acceptable to the user.

The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.

The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.

parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.

System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is Wearable and has a Piezo Air-Pump for Quiet Operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The closed system is separated from a 'milk' side by a flexible diaphragm.

Deformable diaphragm is removably mounted against a part of a breast shield.

Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.

Deformable diaphragm is not physically connected to the piezo air-pump.

Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield

Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

The piezo pump is fed by air that passes through an air filter.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a Piezo Air-Pump and Self-Sealing Diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The closed system is separated from a 'milk' side by the flexible diaphragm.

Deformable diaphragm is removably mounted against a part of a breast shield.

Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.

Deformable diaphragm is not physically connected to the piezo air-pump.

Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.

Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

The piezo pump is fed by air that passes through an air filter.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie Uses More than One Piezo Air Pump in Series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.

An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

Each piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

Each piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

Each piezo pump is fed by air that passes through an air filter.

Each piezo air pump forms part of a closed or closed loop system.

Each piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is Wearable and has a Piezo Air-Pump, a Breast Shield and a Diaphragm that Fits Directly onto the Breast Shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Piezo air pump is position at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum. power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise. The piezo pump is fed by air that passes through an air filter.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is Wearable and has a Piezo Air-Pump for Quiet Operation and a Re-Useable, Rigid Milk Container for Convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

Piezo air pump forms part of a closed or closed loop system.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The closed system is separated from a 'milk' side by a flexible diaphragm.

A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

The deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a Piezo-Pump for Quiet Operation and is a Connected Device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.

The data collection and transmission relates to any other operational data of the system.

Piezo air pump forms part of a closed or closed loop system.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

The closed system is separated from a 'milk' side by a flexible diaphragm.

A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.

The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie Uses a Piezo in Combination with a Heat Sink that Manages the Heat Produced by the Pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48° C. and preferably no more than 43° C.

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.

Heat sink warms a breast shield.

Piezo air pump forms part of a closed or closed loop system.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps, each connected to its own or a shared heat sink.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

The closed system is separated from a 'milk' side by a flexible diaphragm.

A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

The deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

Feature 27 Elvie is Wearable and Gently Massages a Mother's Breast Using Small Bladders Inflated by Air from its Negative Pressure Air-Pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

Air-pump is a piezo pump.

Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.

Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is Wearable and Gently Warms a Mother's Breast Using Small Chambers Inflated by Warm Air from its Negative Pressure Air-Pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.

The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is Wearable and Includes a Re-Useable, Rigid Milk Container that Forms the Lower Part of the Pump, to Fit Inside a Bra Comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is attached to the housing with a push action.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.

The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is Wearable and Includes a Milk Container that Latches to the Housing with a Simple Push to Latch Action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.

Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.

The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.

Mechanism that attaches or latches the milk container into position does so with an audible click.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is Wearable and Includes a Removable Milk Container with an Integral Milk Pouring Spout for Convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

Spout is integral to the milk container.

Spout is integral to a removable lid to the milk container.

Spout is positioned at or close to the front edge of the milk container.

Spout is removable from the container, such as by clipping off the container.

A teat is attachable to the spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast

shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is Wearable and Includes a Removable Milk Container Below the Milk Flow Path Defined by a Breast Shield for Fast and Reliable Milk Collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.

Milk flows from the opening directly into the milk container.

Milk flows from the opening directly into the milk container.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.

Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.

Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is Wearable and Includes a Breast Shield and Removable Milk Container of Optically Clear, Dishwasher Safe Plastic for Ease of Use and Cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

The material is a polycarbonate material, such as Tritan™.

breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is Wearable and Includes Various Components that Self-Seal Under Negative Air Pressure, for Convenience of Assembly and Disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.

The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.

The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.

The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is Wearable and Includes a Spout at the Front Edge of the Milk Container for Easy Pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing,

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.

Spout is integral to a removable lid to the milk container.

Spout is removable from the container, such as by clipping off the container.

A teat is attachable to the spout.

By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.

The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.

The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is Wearable and Includes a Milk Container that is Shaped with Broad Shoulders and that can be Adapted as a Drinking Bottle that Baby can Easily Hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

Teat is attachable directly to the milk container.

Pouring or drinking spout is integral to the milk container.

The shoulders are at least 2 cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.

Spout/teat/straw resides near the edge of the container's rim.

Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.

The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Spout is integral to the milk container.

Spout is integral to a removable lid to the milk container.

Spout is positioned at or close to the front edge of the milk container.

Spout is removable from the container, such as by clipping off the container.

A teat is attachable to the spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is Wearable and Includes a Light-Based System that Measures the Quantity of Milk in the Container for Fast and Reliable Feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;

(b) at least one light emitter, configured to direct radiation towards the surface of the milk;

(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.

Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.

Milk-flow data is captured and stored.

If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 the Separate IR Puck for Liquid Quantity Measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

The quantity of milk is measured as milk enters the container or as milk is removed from the container.

Measured property includes the reflected light intensity

Feature 39 the Separate IR Puck Combined with Liquid Tilt Angle Measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

Measured property includes the reflected light intensity

The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally Applicable Optional Features

Weight of the entire unit, unfilled, is under 250 g and preferably 214 g.

Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.

Housing includes a rechargeable battery.

System is self-contained.

System is a closed loop system.

Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.

Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.

Bra adjuster is extensible or elastic.

Bra adjuster is of a fixed length.

Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.

Bra adjuster is machine-washing washable.

F. Other Features that can sit outside the breast pump context

Feature 41 Wearable Device Using More than One Piezo Pump Connected in Series or in Parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

The wearable device is a medical wearable device.

The piezo pumps air or any liquid etc.

The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable Medical Device Using a Piezo Pump and a Heat Sink Attached Together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

The wearable device uses more than one piezo pump connected in series.

The wearable device uses more than one piezo pump connected in parallel.

Each piezo pump is connected to its own heat sink, or to a common heat sink.

The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48° C. and preferably no more than 43° C.

The wearable device includes a thermal cut out.

Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.

Use cases application:

Wound therapy

High degree burns

Sleep apnea

Deep vein thrombosis

Sports injury.

Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of the present invention. While the present invention has been shown in the drawings and fully

described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

The invention claimed is:

1. A breast pump device comprising:

a self-contained, in-bra wearable device comprising:

a pump housing that includes:

a rechargeable battery,

a power charging circuit for controlling charging of the rechargeable battery,

control electronics powered by the rechargeable battery,

a pump powered by the rechargeable battery and configured to generate negative air pressure,

a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery, and

a recess or cavity that defines a pumping chamber;

a breast shield made up of a breast flange and a nipple tunnel;

a milk container that is configured to be attached to and removed from the pump housing; and

a diaphragm that is configured to prevent milk from reaching the pump, the diaphragm being seated against a diaphragm housing that is fixed to a recessed surface of the pump housing, and the diaphragm being a membrane that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

2. The breast pump device of claim **1**, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

3. The breast pump device of claim **1**, wherein the breast shield is a one piece item that in use presents a single continuous surface to a nipple and a breast.

4. The breast pump device of claim **1**, wherein the breast shield has a top and bottom when positioned upright for normal use, and

wherein the breast shield is generally symmetrical about a center-line running from the top to the bottom of the breast shield when positioned upright for normal use.

5. The breast pump device of claim **1**, wherein the breast shield is configured to slide in and out from the pump housing, together with the diaphragm that prevents milk from reaching the pump.

6. The breast pump device of claim **1**, wherein the breast pump device includes only the breast shield and the milk container that are directly removable from the pump housing in normal use or normal dis-assembly.

7. The breast pump device of claim **1**, wherein the diaphragm is substantially circular and the diaphragm housing is substantially circular.

8. The breast pump device of claim **1**, wherein the milk container is substantially rigid.

9. The breast pump device of claim **1**, wherein the milk container is configured to attach to a lower part of the pump housing and to form a flat bottomed base for the breast pump device.

10. The breast pump device of claim **1**, wherein the milk container has a surface shaped to continue a curved shape of the pump housing so that the breast pump device can be held comfortably inside a bra.

11. The breast pump device of claim **1**, wherein the milk container is attachable to the pump housing with a mechanical or magnetic mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the pump housing with a single push action.

12. The breast pump device of claim **1**, wherein the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows under gravity into the milk container.

13. The breast pump device of claim **1**, wherein the diaphragm defines a milk-flow side chamber on one side of the diaphragm and an air-side chamber on the other side of the diaphragm.

14. The breast pump device of claim **1**, wherein the diaphragm is configured to self-seal under negative pressure around its outer edge, to form a watertight and airtight seal around the recess or cavity in the pump housing.

15. The breast pump device of claim **1**, wherein the diaphragm housing is a first diaphragm housing, and

wherein the breast pump device further comprises a second diaphragm housing attached to the nipple tunnel and configured to define a milk-flow side chamber, the diaphragm being configured to be positioned between the first diaphragm housing and the second diaphragm housing.

16. The breast pump device of claim **15**, wherein the diaphragm is configured to be releasably secured around an edge of the second diaphragm housing.

17. The breast pump device of claim **15**, wherein the second diaphragm housing is positioned, when the breast pump device is upright, over a top surface of the nipple tunnel.

18. The breast pump device of claim **15**, wherein the second diaphragm housing includes an air hole to transfer negative air pressure to the nipple tunnel.

19. The breast pump device of claim **15**, wherein the diaphragm is a flexible and generally circular diaphragm and the second diaphragm housing has a corresponding generally circular shape.

20. The breast pump device of claim **15**, wherein the second diaphragm housing is an integral part of the breast shield.

21. The breast pump device of claim **15**, wherein the diaphragm is configured to be attached around an edge of the second diaphragm housing.

22. The breast pump device of claim **15**, wherein the diaphragm is configured to seal, self-seal, self energizing seal or interference fit seal against the first diaphragm housing.

23. The breast pump device of claim **1**, wherein the diaphragm is a flexible and generally circular diaphragm.

24. The breast pump device of claim **1**, wherein the diaphragm is a flexible and generally circular diaphragm that, in a relaxed state, includes an inner raised area and a concentric outer raised area.

25. The breast pump device of claim **1**, wherein the milk container is configured to be pressed or pushed into engagement with the pump housing.

26. The breast pump device of claim **1**, wherein the self-contained, in-bra wearable device is configured so that expressed milk flows under gravity through an opening in the nipple tunnel and into the milk container through a duck-bill valve that stays sealed when there is negative air pressure being applied by the pump to ensure that negative air pressure is not applied to the milk container.

27. The breast pump device of claim **1**, wherein the milk container comprises a curved surface that includes a flat area that serves as a base for the milk container.

28. The breast pump device of claim **1**, wherein the milk container has a curved surface configured to enable the breast pump device to be held comfortably in a bra.

29. A breast pump device that is configured as a self-contained, in-bra wearable device, the breast pump device comprising:

a self-contained, in-bra wearable device comprising:

a housing that includes:

a rechargeable battery,

a power charging circuit for controlling charging of the rechargeable battery,

control electronics powered by the rechargeable battery,

a pump powered by the rechargeable battery and configured to generate negative air pressure, and

a Universal Serial Bus (USB) charging socket for transferring power to the power charging circuit and the rechargeable battery;

a breast shield made up of a breast flange and a nipple tunnel;

a milk container that is configured to be attached to and removed from the housing; and

a membrane that is configured to define a pumping chamber at least in part with an external surface of the housing, the membrane configured to deform in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel.

30. The breast pump device of claim **29**, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

31. The breast pump device of claim **29**, wherein the breast shield is a one piece item that in use presents a single continuous surface to a nipple and a breast.

32. The breast pump device of claim **29**, wherein the breast shield has a top and bottom when positioned upright for normal use, and

wherein the breast shield is generally symmetrical about a center-line running from the top to the bottom of the breast shield when positioned upright for normal use.

33. The breast pump device of claim **29**, wherein the breast pump device includes only the breast shield and the milk container that are directly removable from the housing in normal use or normal dis-assembly.

34. The breast pump device of claim **29**, wherein the membrane is substantially circular.

35. The breast pump device of claim **29**, wherein the milk container is substantially rigid.

36. The breast pump device of claim **29**, wherein the milk container has a surface shaped to continue a curved shape of the housing so that the breast pump device can be held comfortably inside a bra.

37. The breast pump device of claim **29**, wherein the milk container is attachable to the housing with a mechanical or magnetic mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

38. The breast pump device of claim **29**, wherein the nipple tunnel includes on a lower surface of the nipple tunnel an opening through which expressed milk flows under gravity into the milk container.

39. The breast pump device of claim **29**, wherein the membrane defines a milk-flow side chamber on one side of the membrane and an air-side chamber on the other side of the membrane.

40. The breast pump device of claim **29**, wherein the membrane is configured to self-seal under negative pressure around its outer edge, to form a watertight and airtight seal around the recess or cavity in the housing.

41. The breast pump device of claim **29**, the membrane is a flexible membrane.

42. The breast pump device of claim **29**, wherein the membrane is a flexible and generally circular membrane that, in a relaxed state, includes an inner raised area and a concentric outer raised area.

43. The breast pump device of claim **29**, wherein the milk container is configured to be pressed or pushed into engagement with the housing.

44. The breast pump device of claim **29**, wherein the self-contained, in-bra wearable device is configured so that expressed milk flows under gravity through an opening in the nipple tunnel and into the milk container through a duck-bill valve that stays sealed when there is negative air pressure being applied by the pump to ensure that negative air pressure is not applied to the milk container.

45. The breast pump device of claim **29**, wherein the milk container comprises a curved surface that includes a flat area that serves as a base for the milk container.

46. The breast pump device of claim **29**, wherein the milk container has a curved surface configured to enable the breast pump device to be held comfortably in a bra.

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Exhibit 25

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(12) **United States Patent**
De Becdelievre et al.

(10) **Patent No.: US 11,806,454 B2**
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(54) **WEARABLE BREAST PUMP SYSTEM**

(71) Applicant: **Chiaro Technology Limited**, London (GB)

(72) Inventors: **Thibault De Becdelievre**, London (GB); **Oliver Blanchard**, London (GB); **Georgia Thomas**, Bristol (GB); **Daniel John Thompson**, Bristol (GB); **Adam Rollo**, London (GB); **Paul Reid**, Bristol (GB); **Jonathan O'Toole**, Bristol (GB); **Jack Biltcliffe**, London (GB); **Clare Larkspur**, Bristol (GB); **Claudia Bruen**, London (GB)

(73) Assignee: **Chiaro Technology Limited**, London (GB)

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(22) Filed: **Dec. 30, 2022**

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Related U.S. Application Data

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(30) **Foreign Application Priority Data**

Mar. 26, 2020 (GB) 2004395

(51) **Int. Cl.**

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A61M 1/00	(2006.01)
A61M 39/22	(2006.01)

(52) **U.S. Cl.**
CPC ***A61M 1/067*** (2021.05); ***A61M 1/60*** (2021.05); ***A61M 39/22*** (2013.01); *A61M 2205/42* (2013.01); *A61M 2209/088* (2013.01)

(58) **Field of Classification Search**
CPC A61M 1/06–0697
See application file for complete search history.

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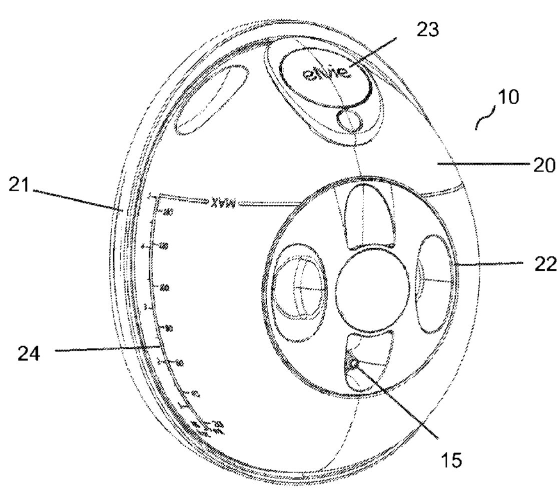
Primary Examiner — Courtney B Fredrickson
(74) *Attorney, Agent, or Firm* — Sterne, Kessler, Goldstein & Fox P.L.L.C.

(57) **ABSTRACT**

A breast pump system comprises at least one wearable milk collection hub connected via an air line to a combined external air pump and control unit. Each milk collection hub comprises: (a) a breast shield made up of a breast flange and a nipple tunnel; (b) a flexible diaphragm that is configured to prevent milk from reaching the external air pump; (c) an outer shell that is configured to removably attach to the breast shield, such that, when attached, the breast shield and outer shell form a vessel for collecting milk; and (d) a diaphragm cap that is configured to be secured over the
(Continued)



diaphragm, forms part of the front face of the outer shell, and includes a port connected to the air line.

33 Claims, 34 Drawing Sheets

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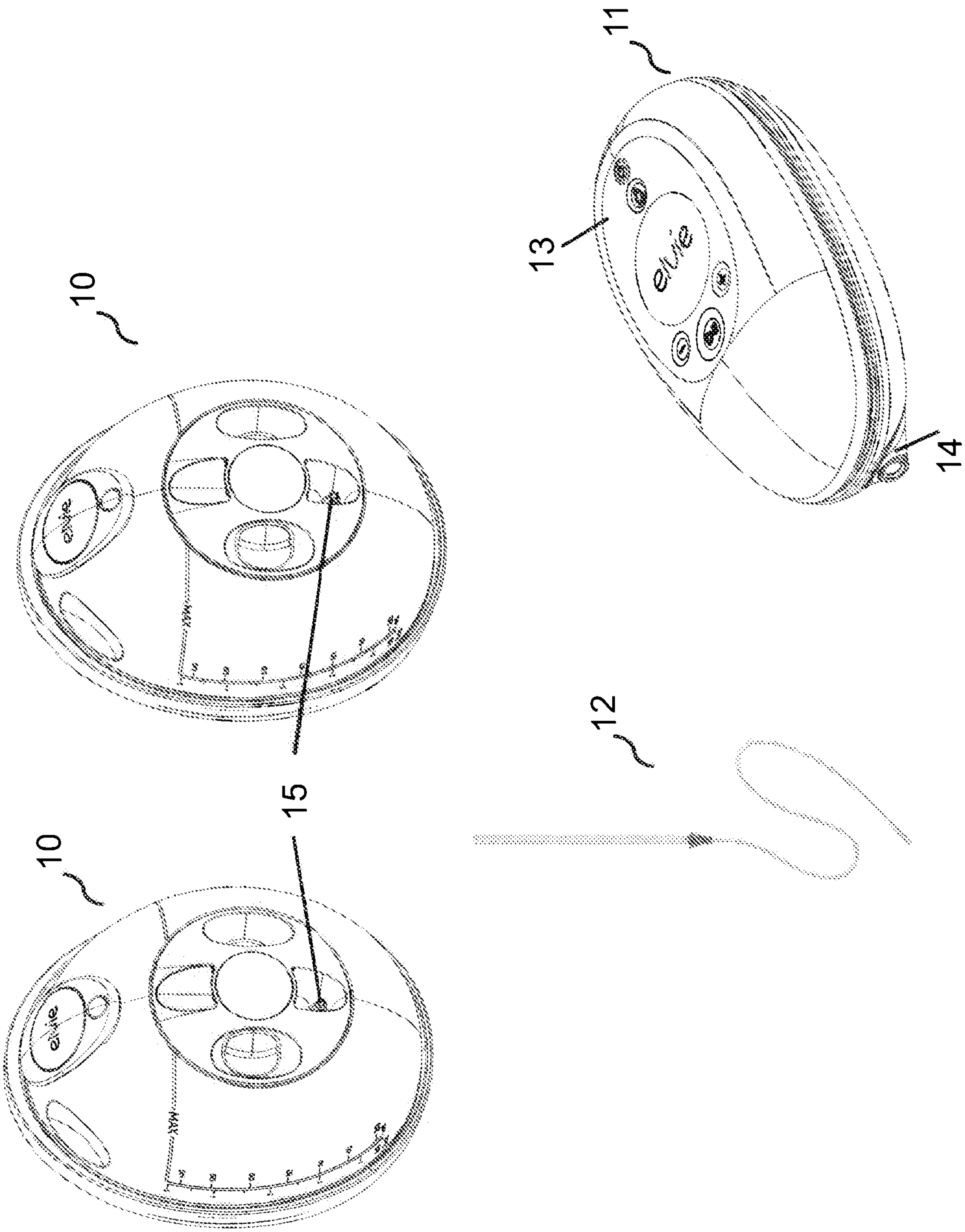

FIGURE 1A

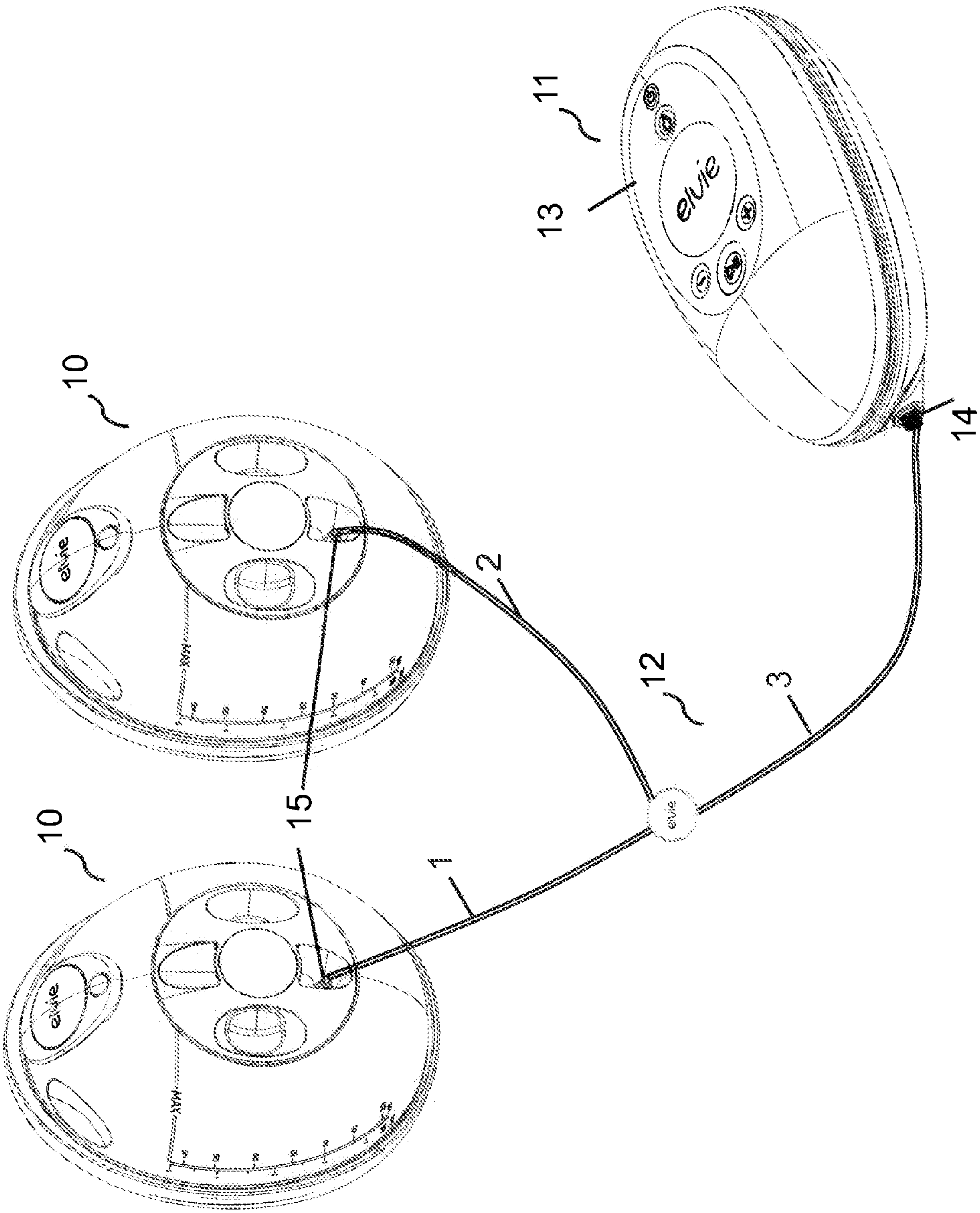

FIGURE 1B

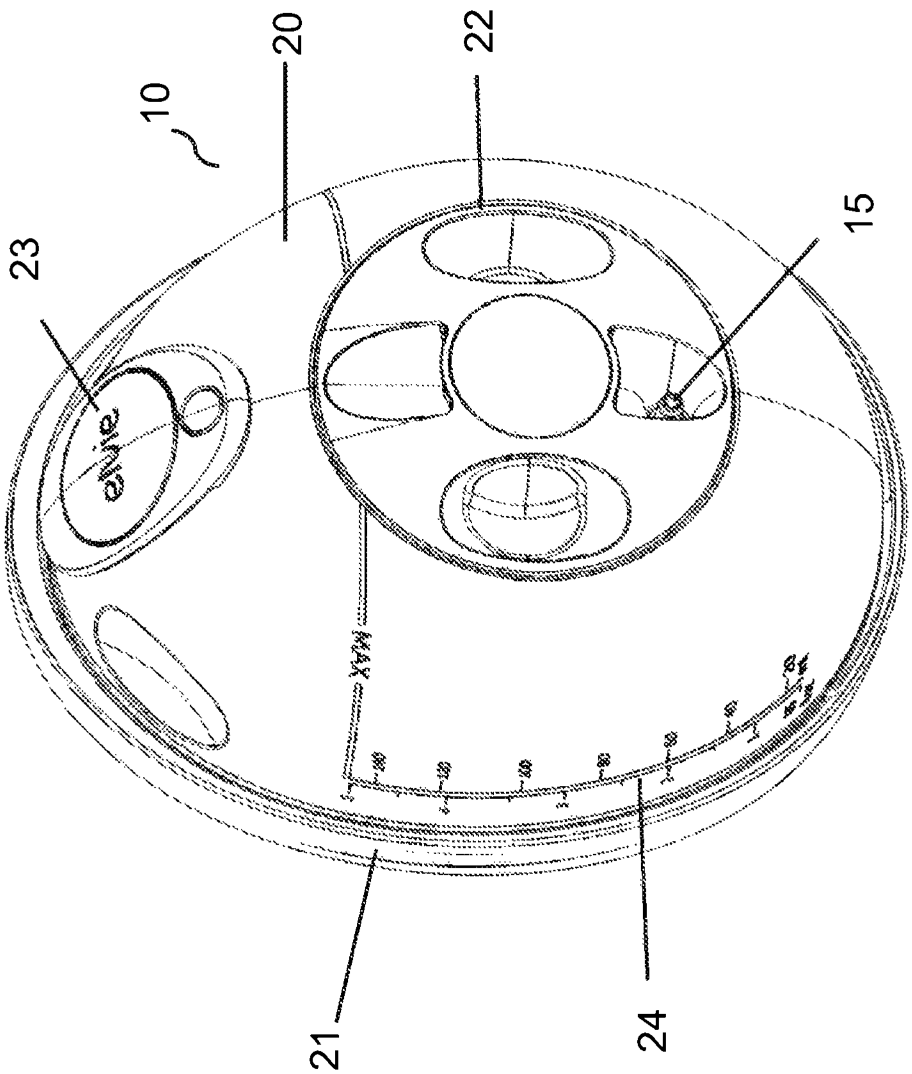

FIGURE 2

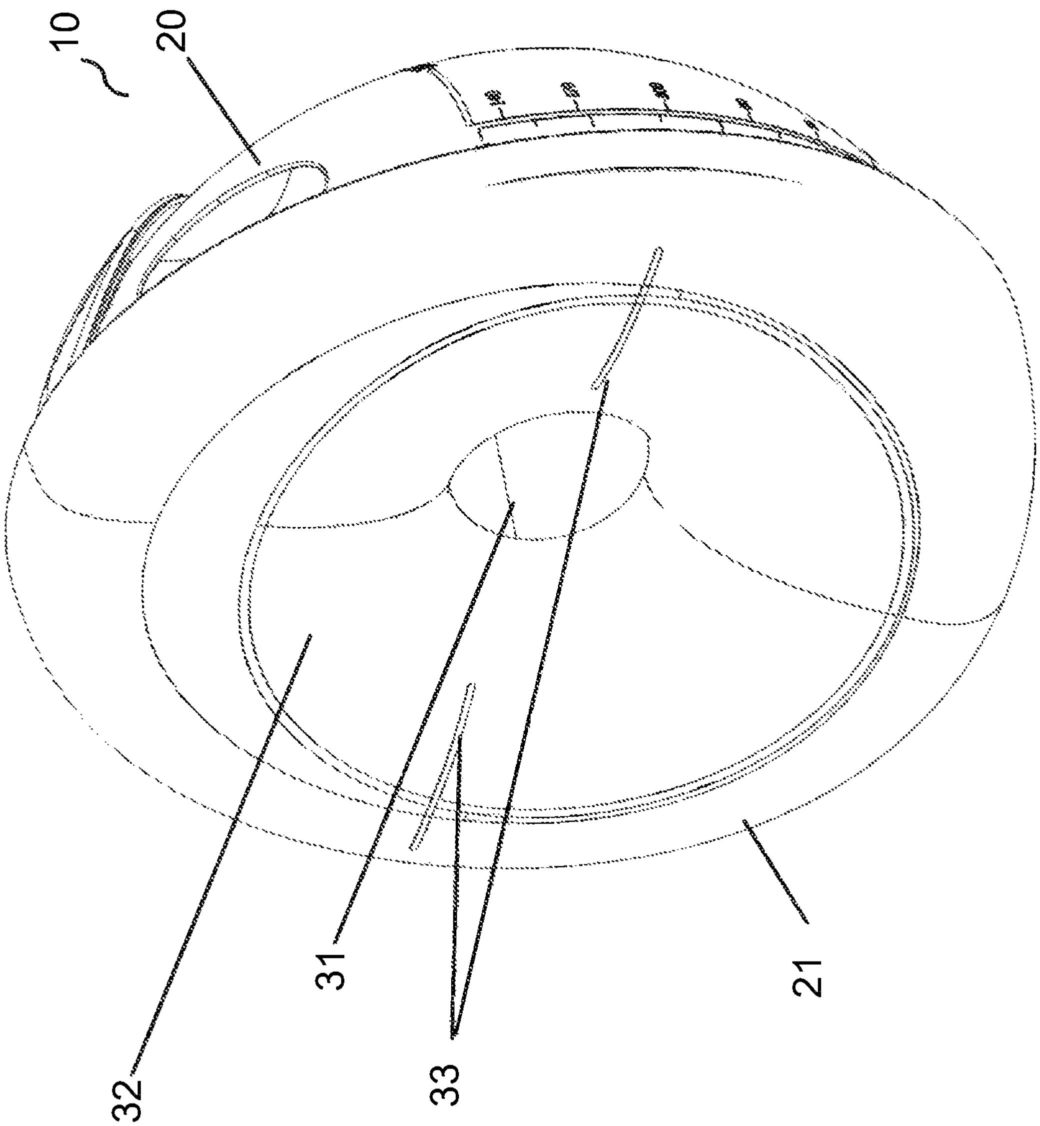

FIGURE 3

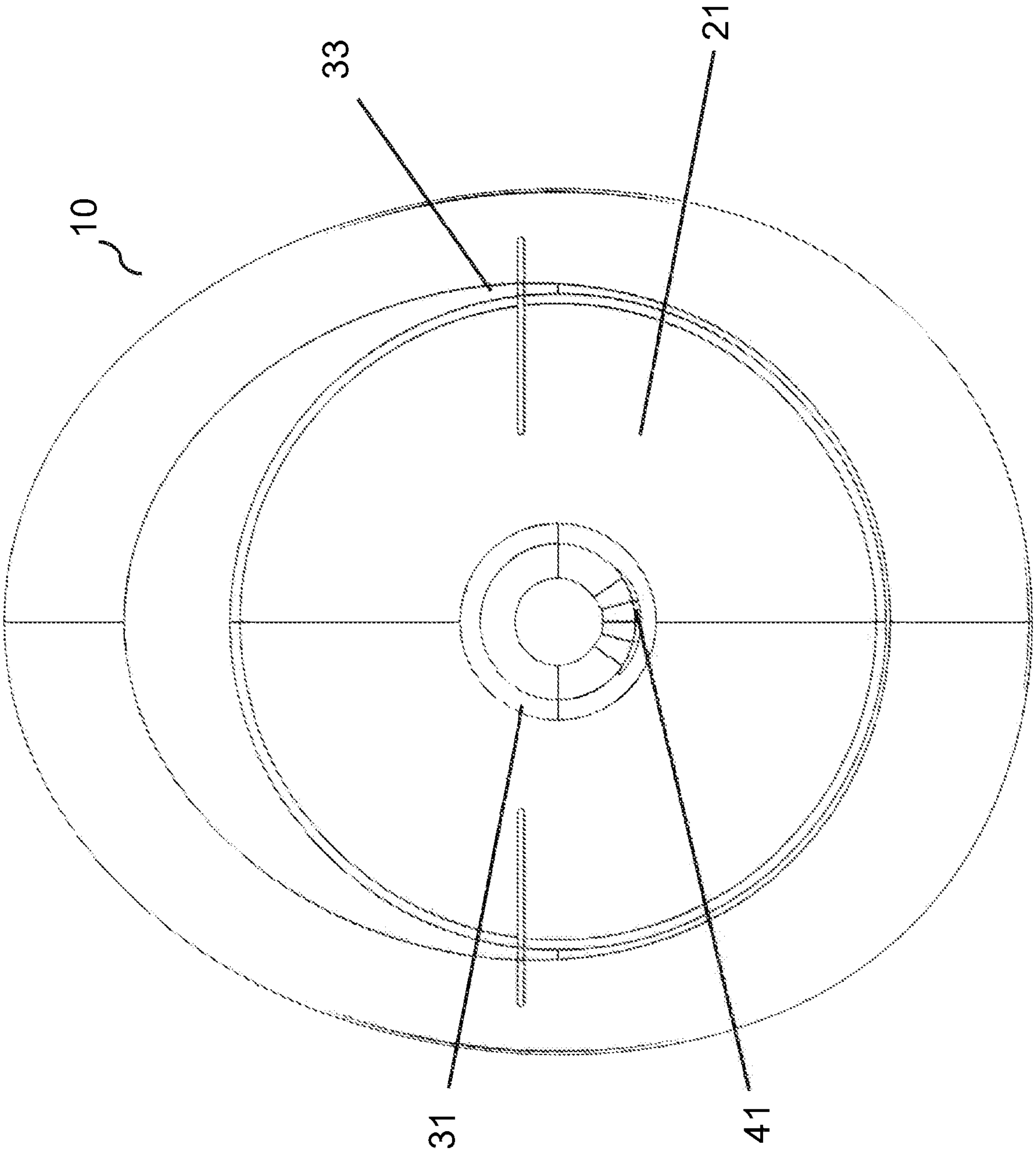

FIGURE 4

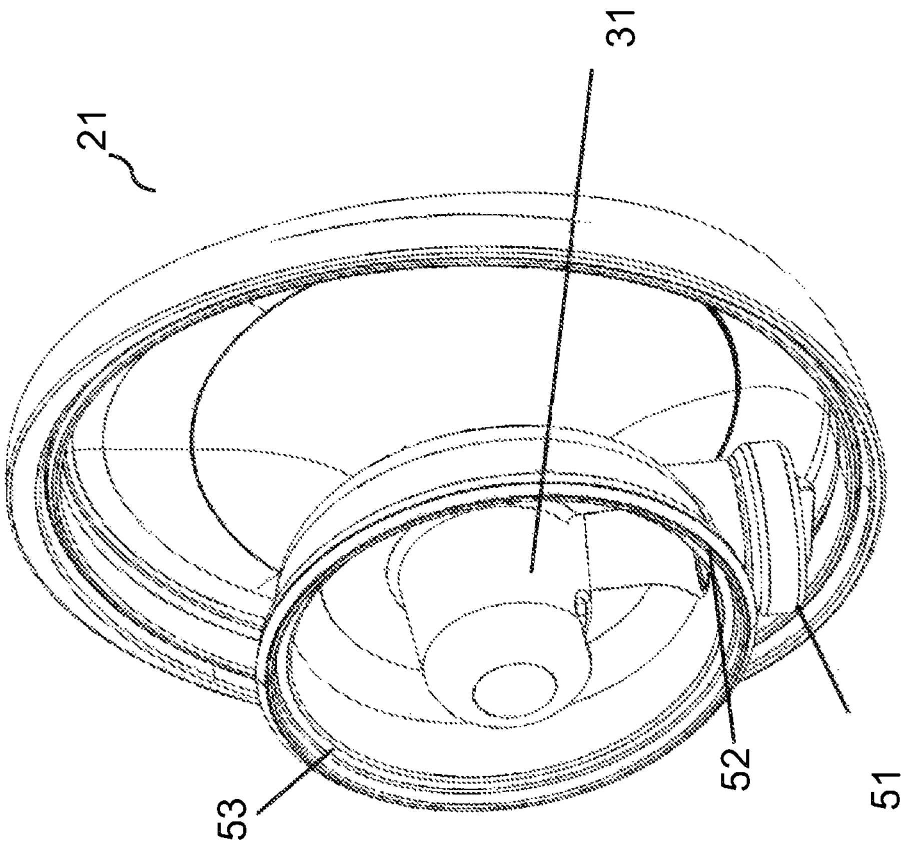

FIGURE 5

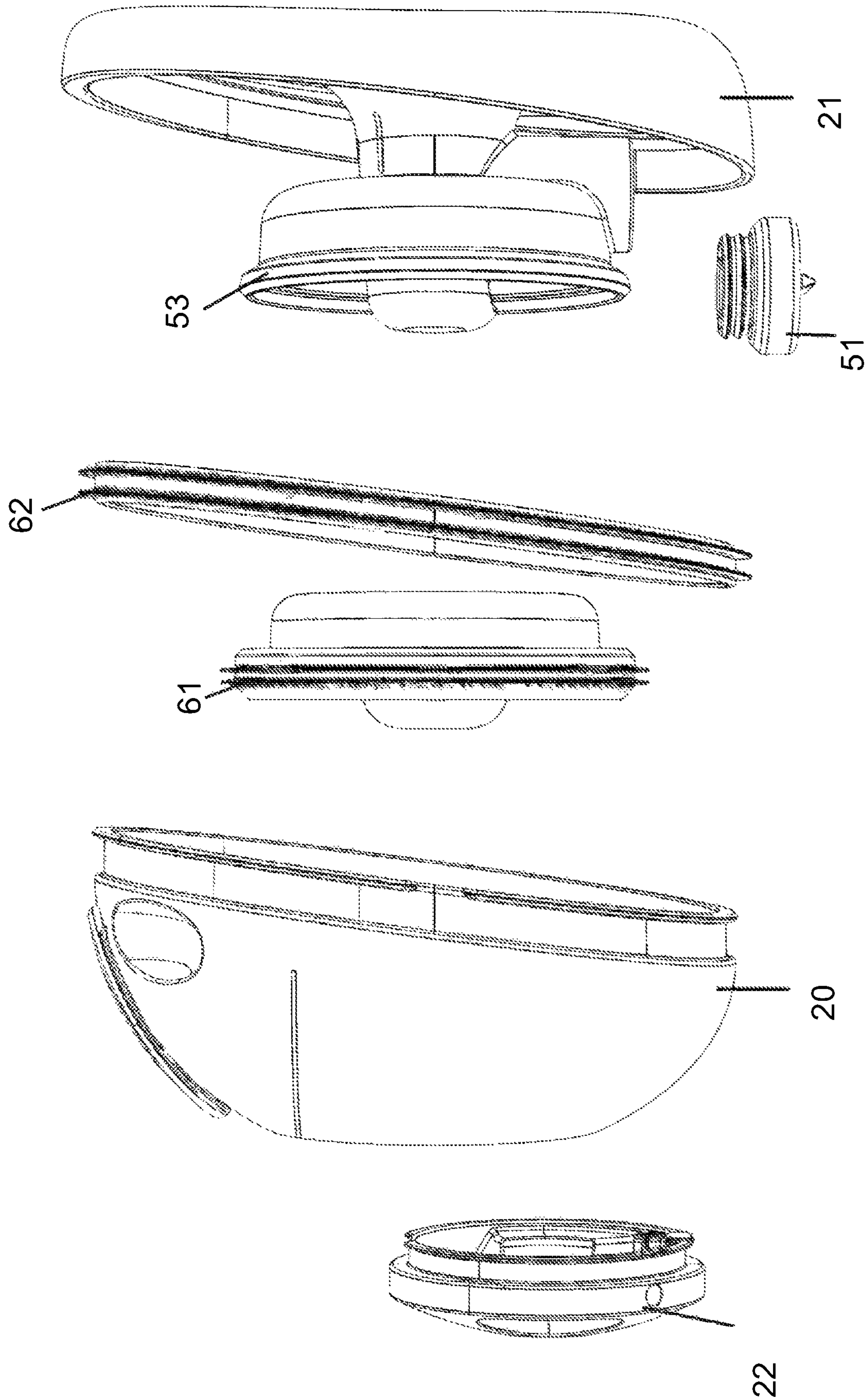

FIGURE 6

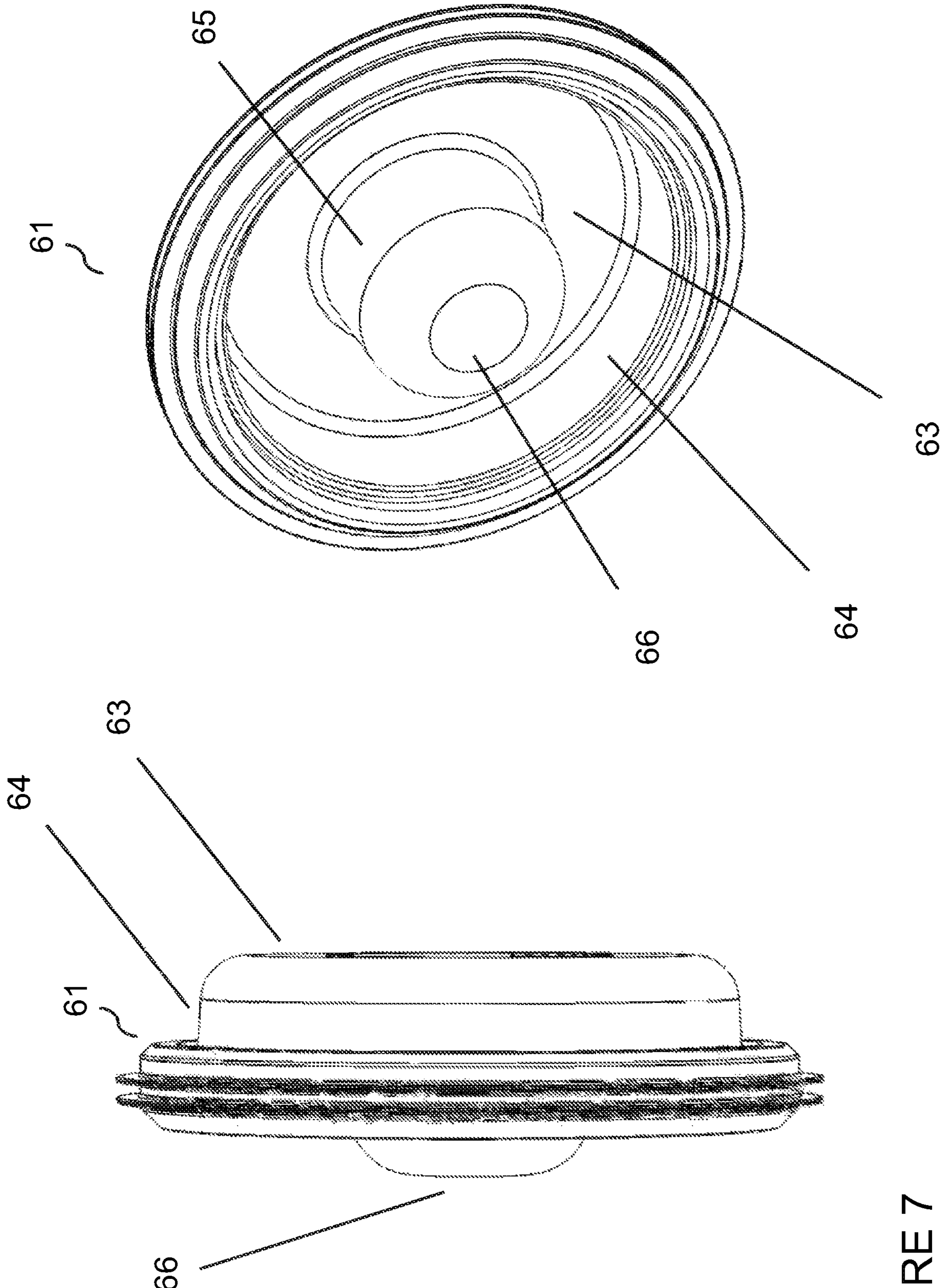

FIGURE 7

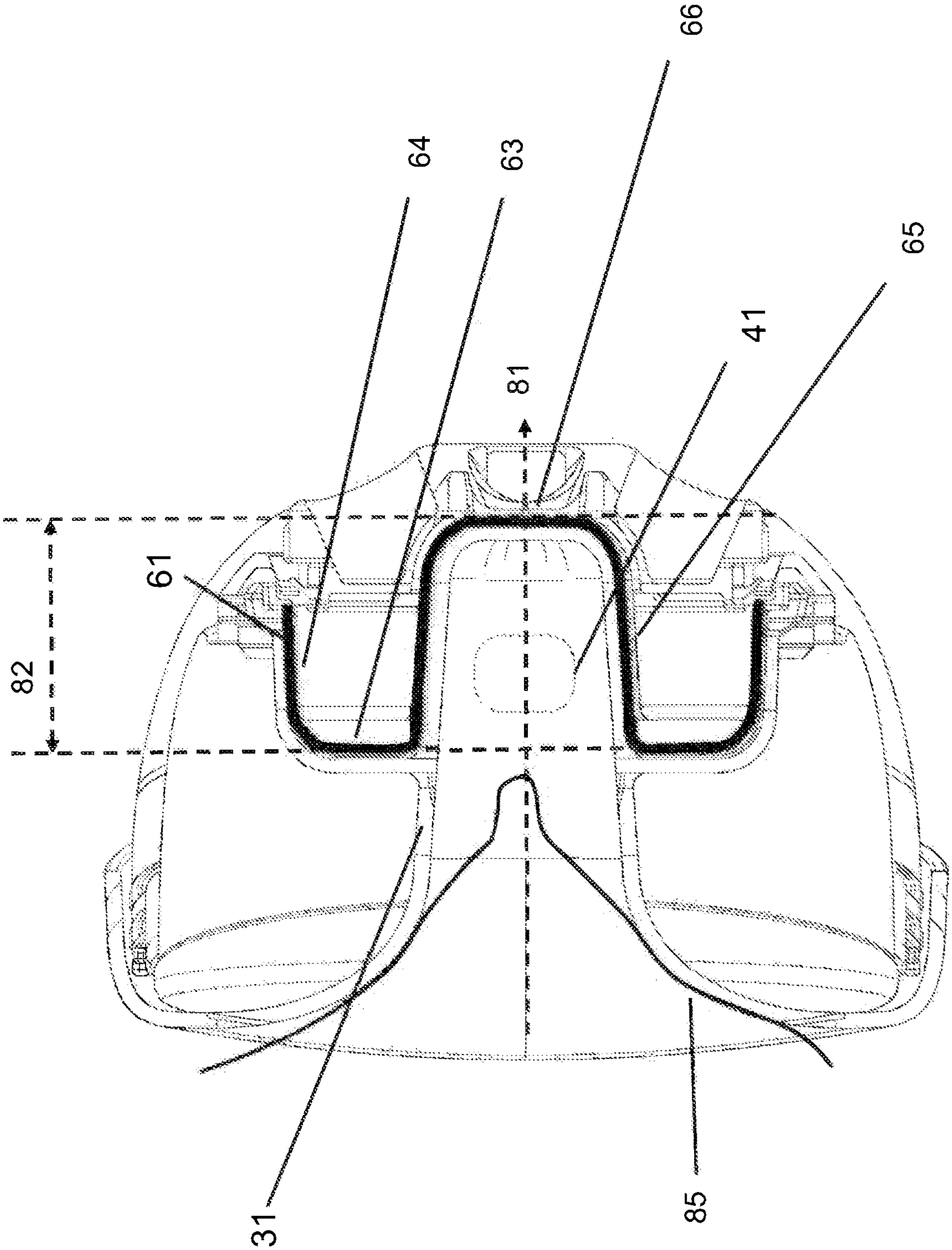

FIGURE 8

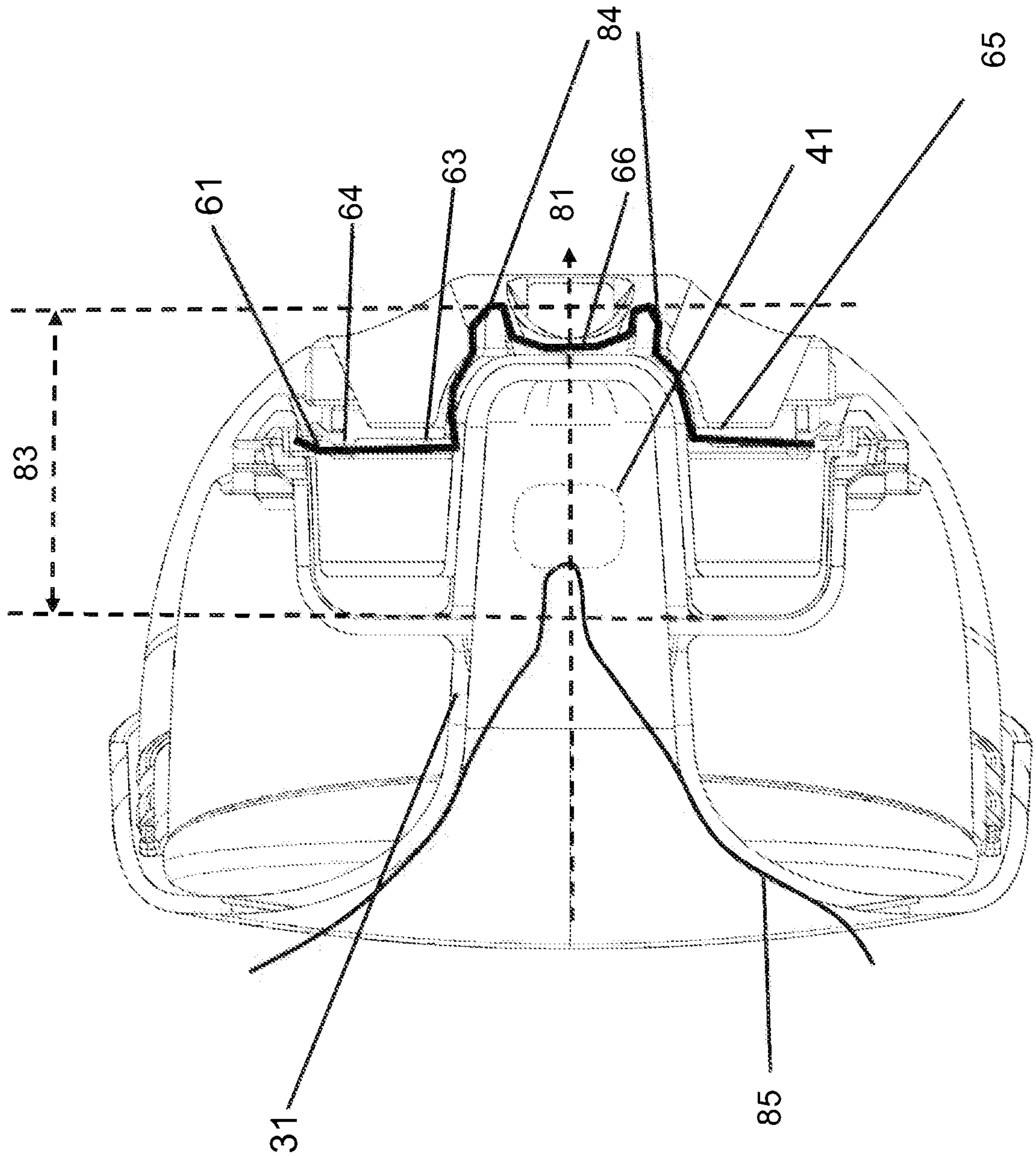

FIGURE 9

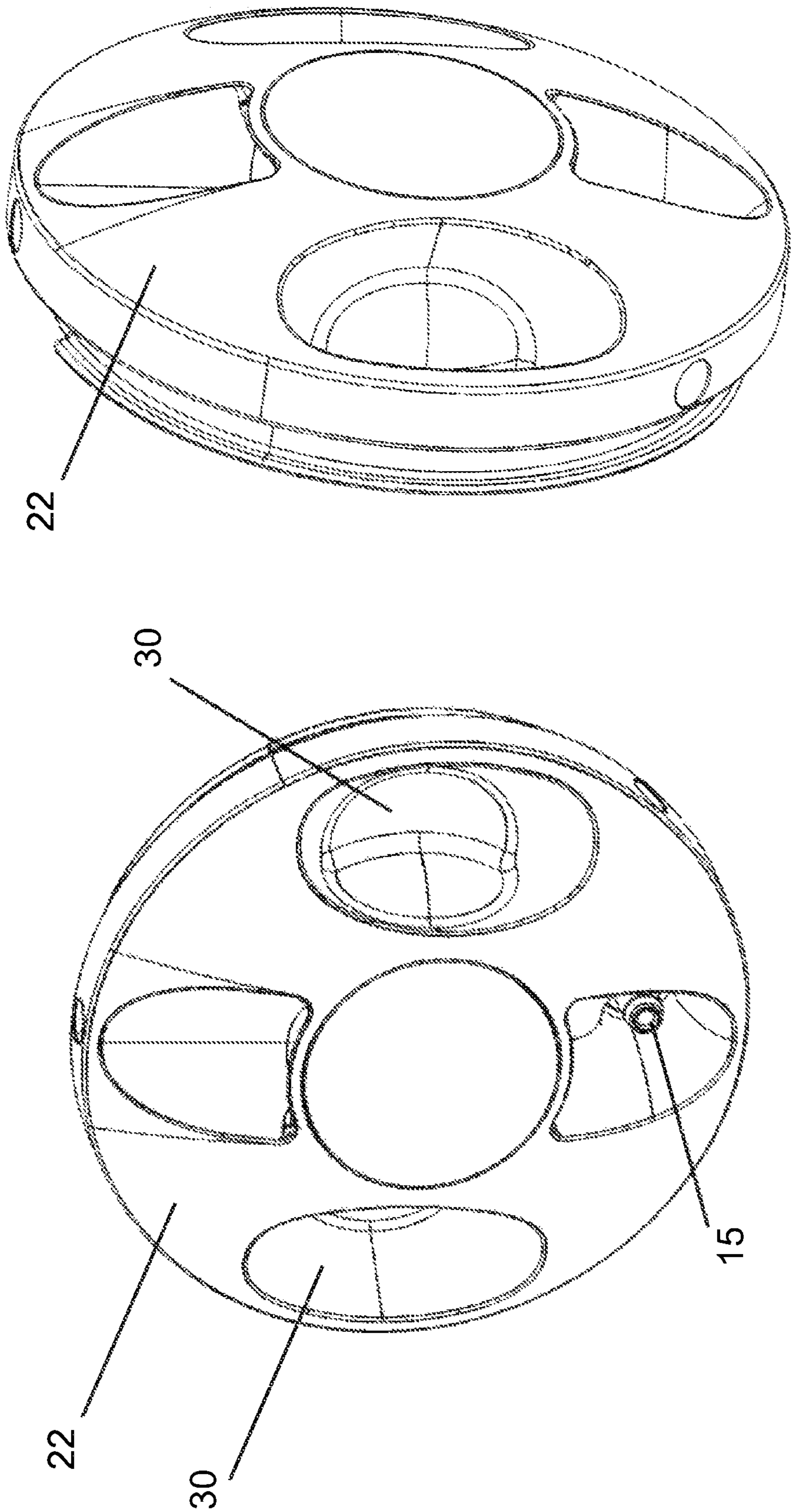

FIGURE 10

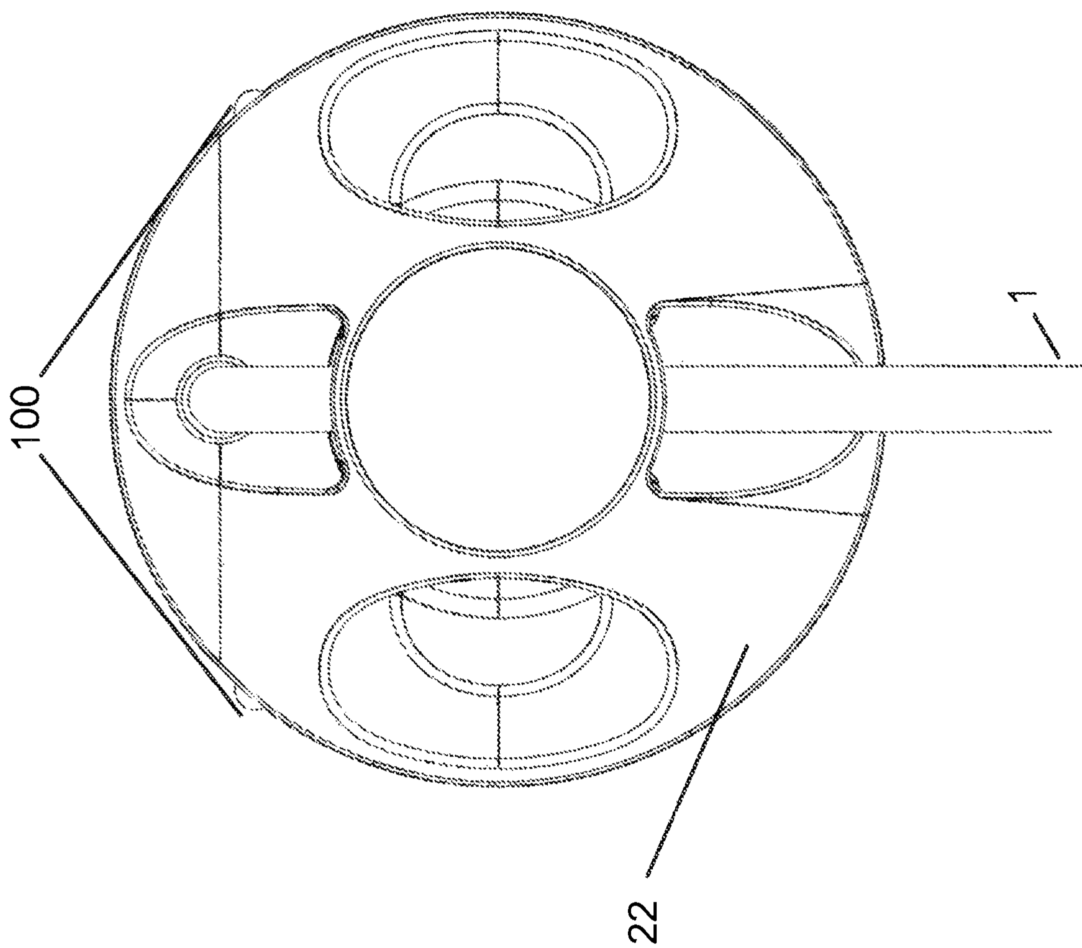

FIGURE 11

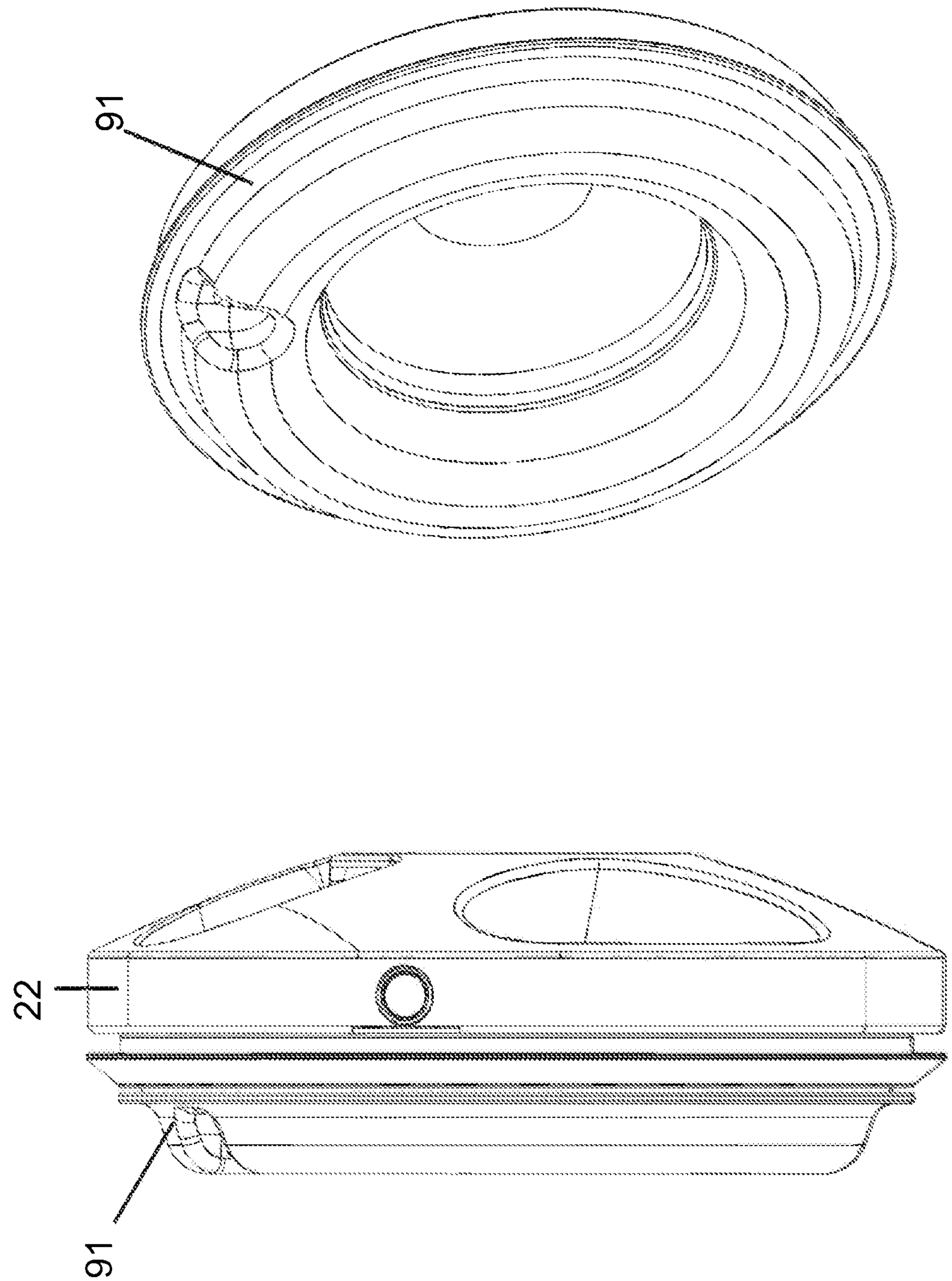

FIGURE 12

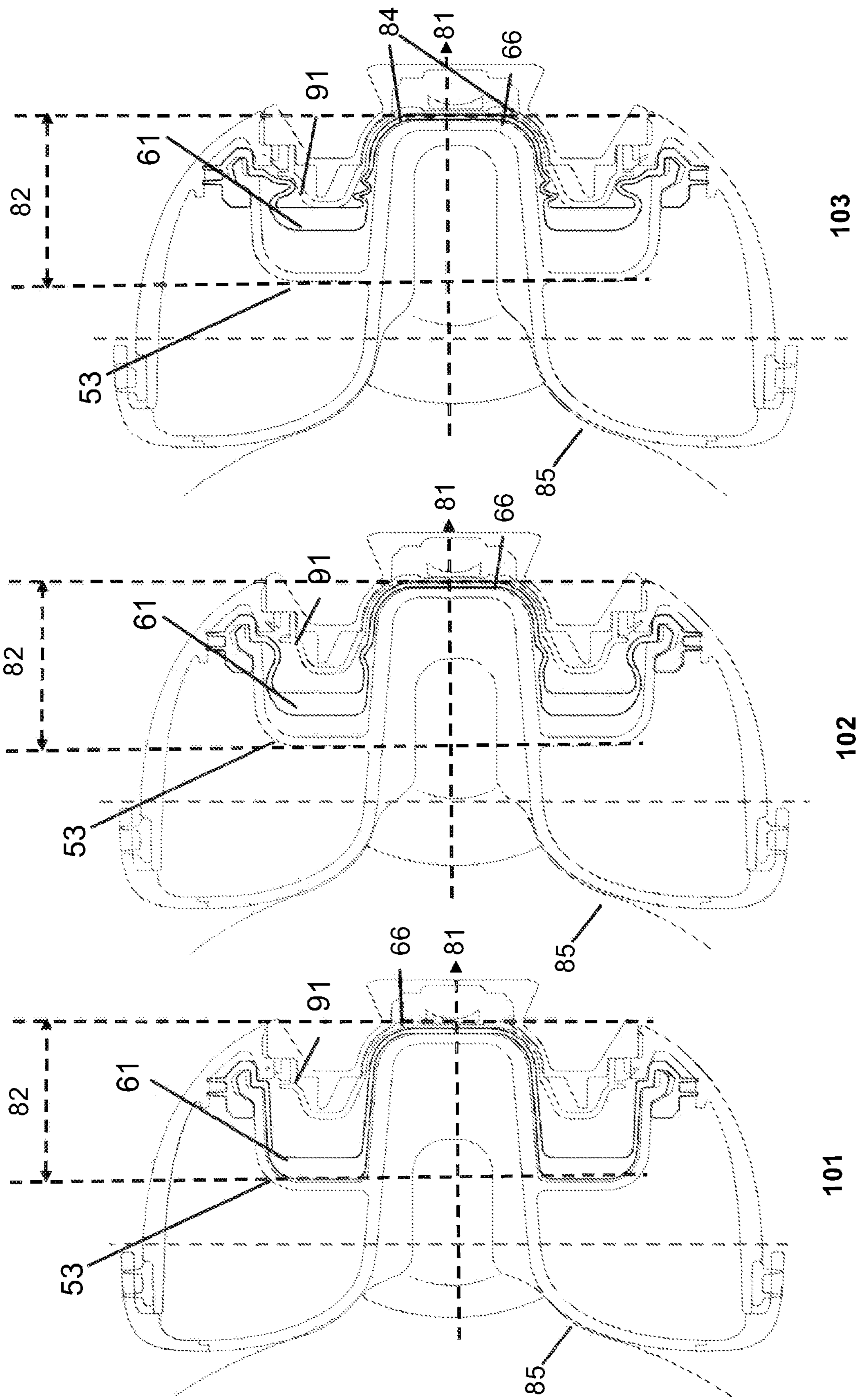
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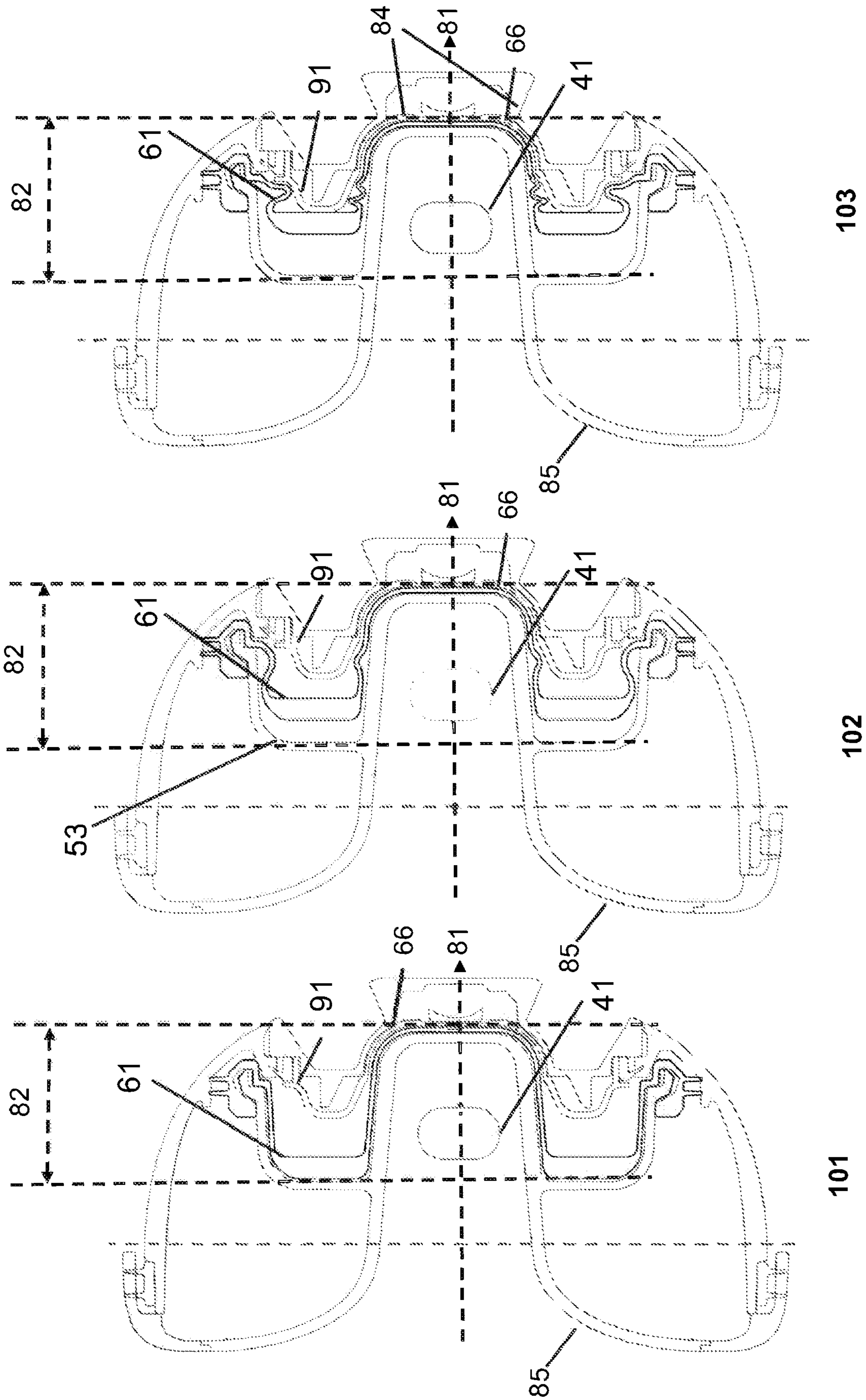
FIGURE 13A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41
61
82
101
85

FIGURE 13B

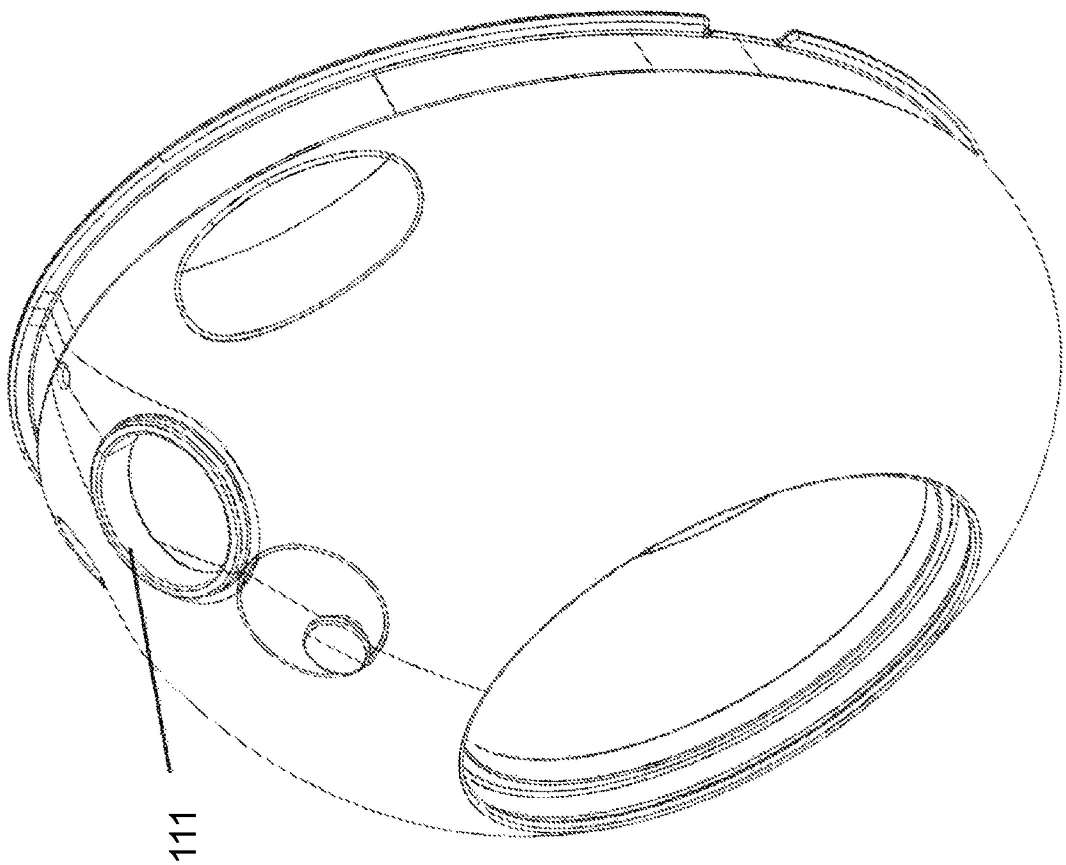


FIGURE 14

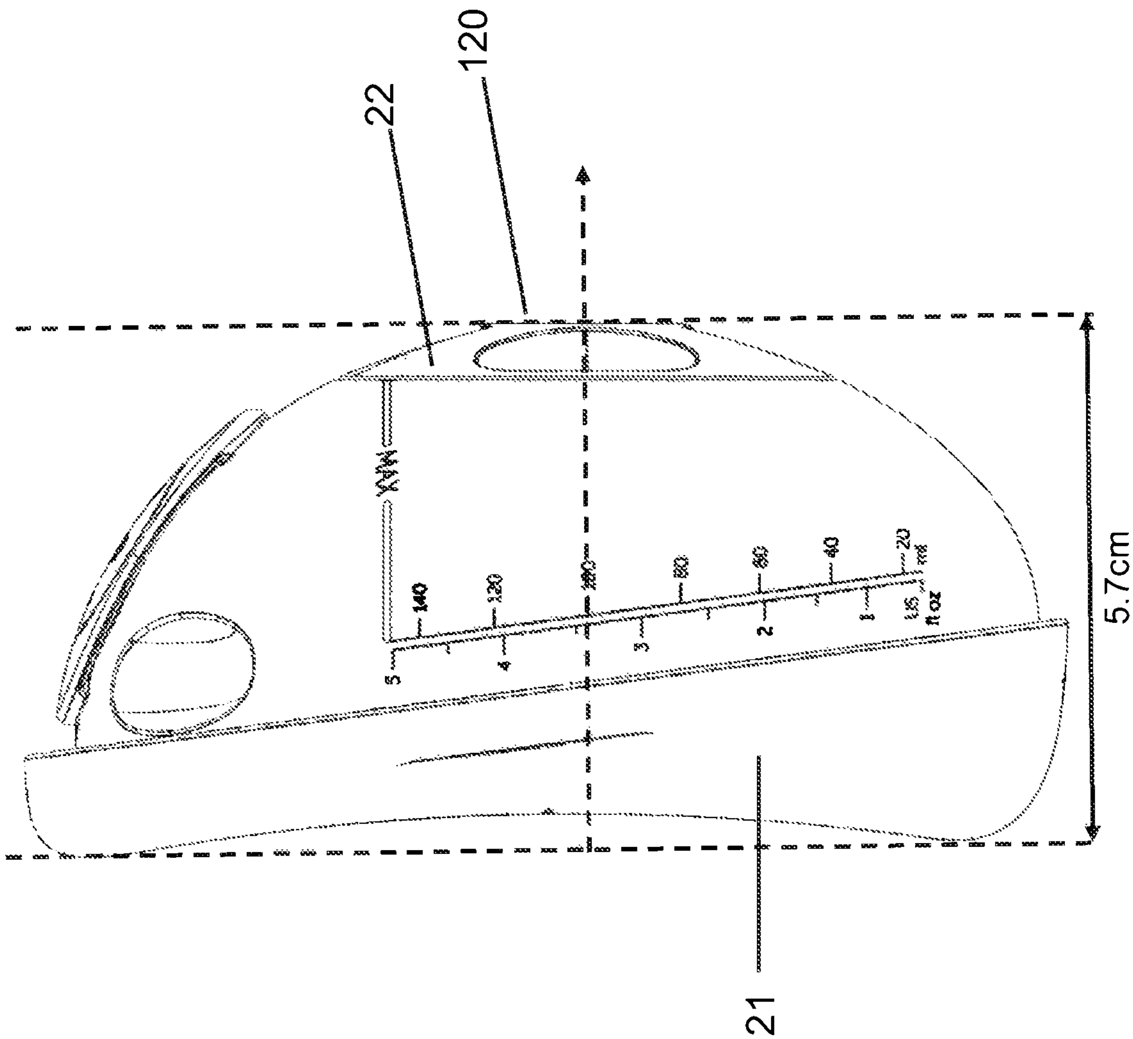


FIGURE 15

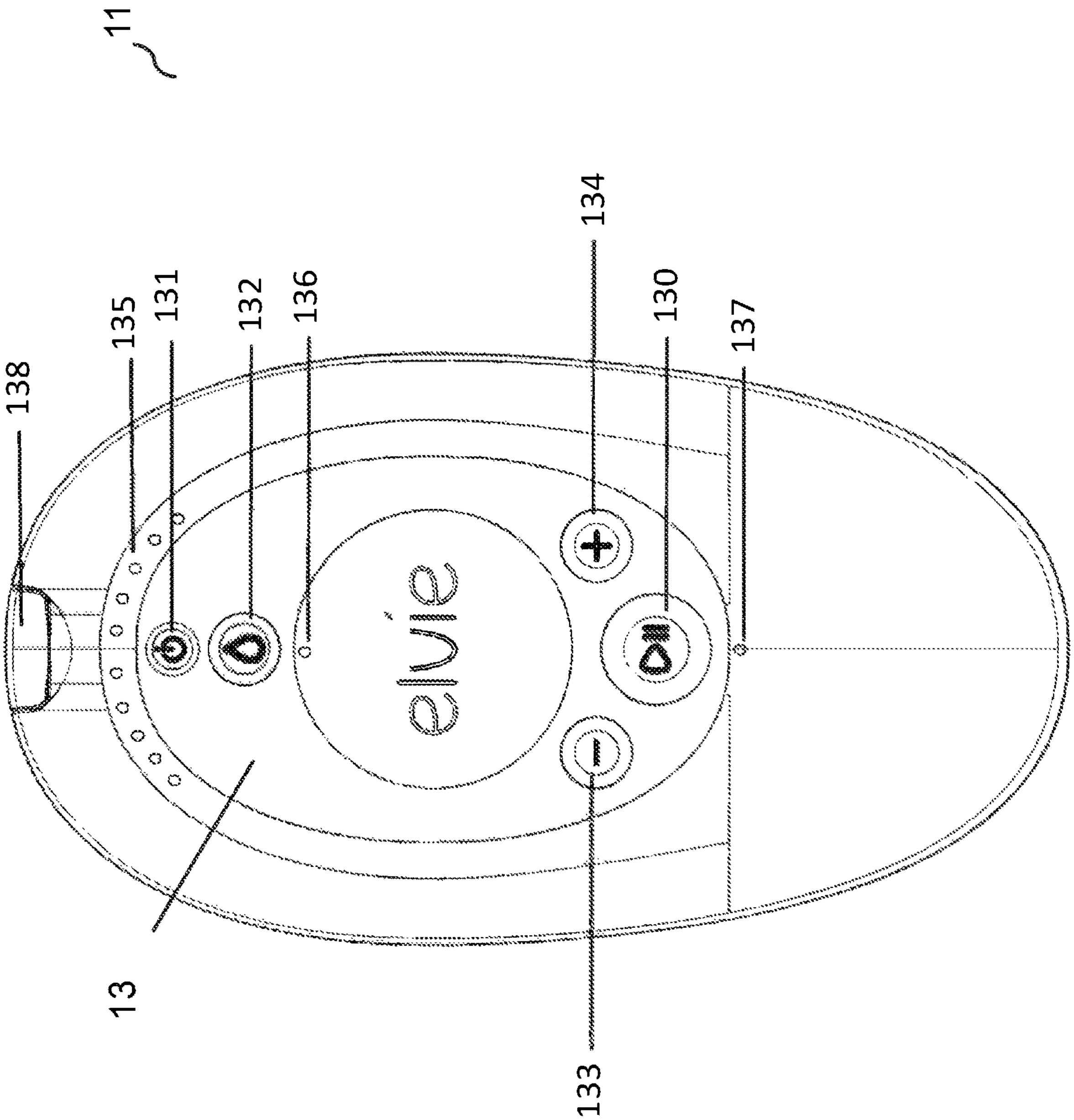


FIGURE 16

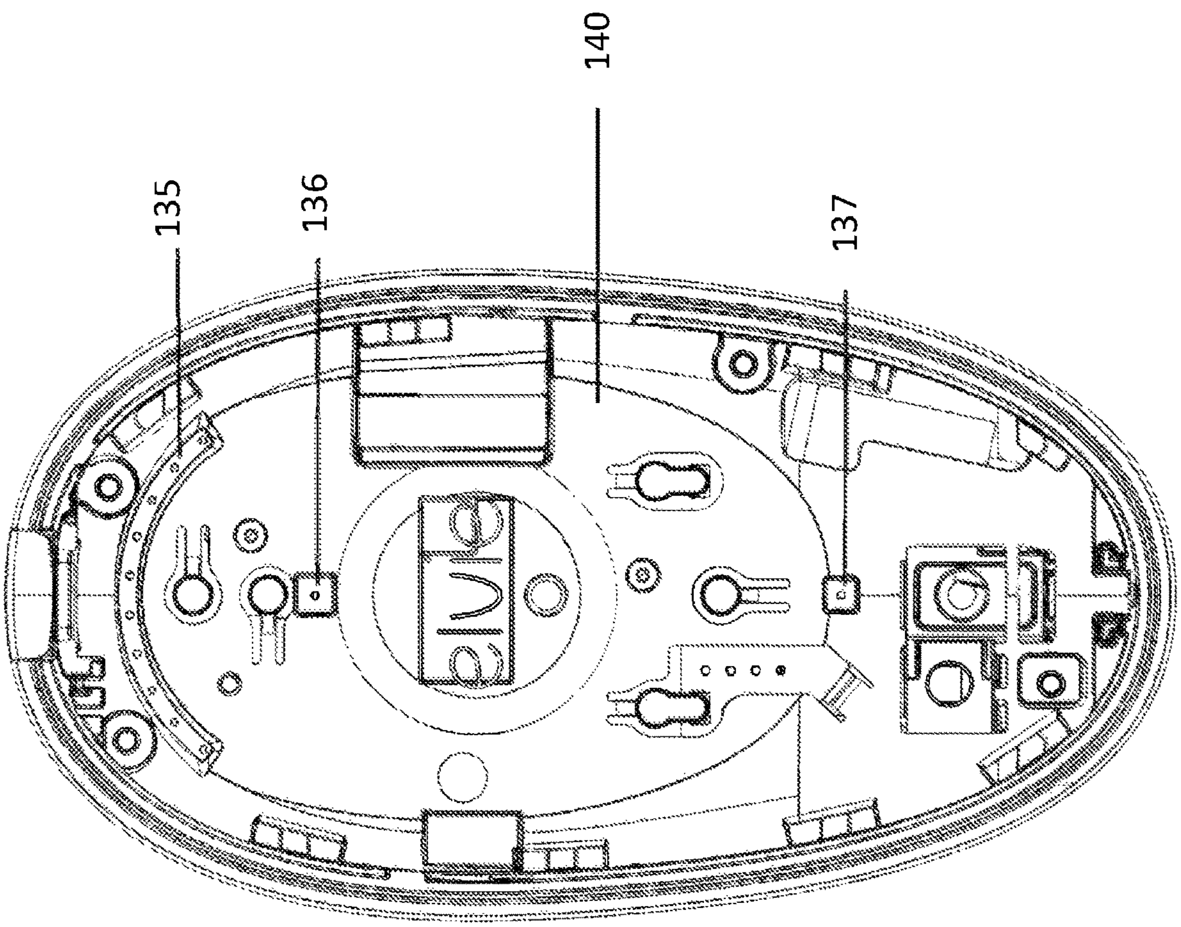


FIGURE 17

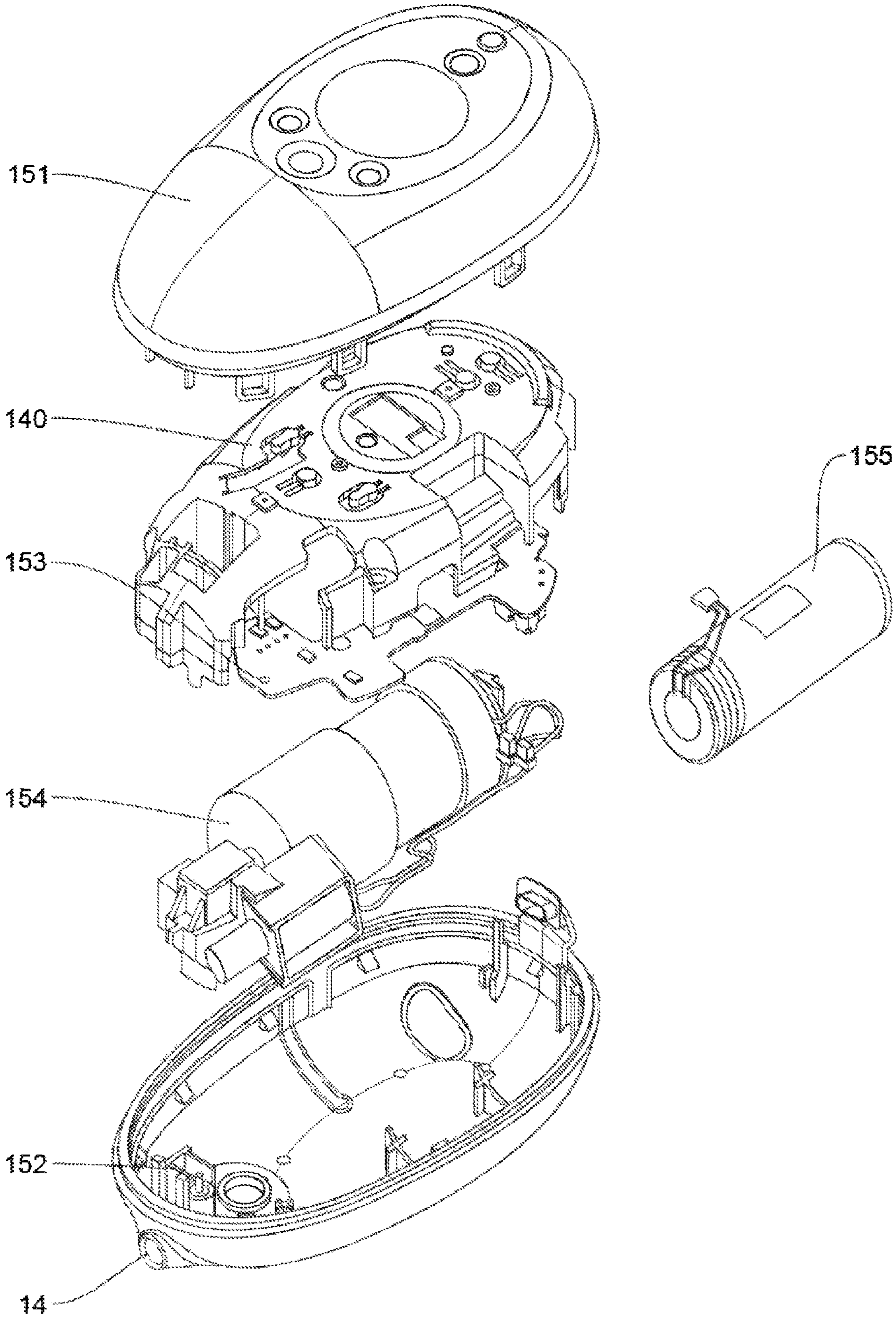


FIGURE 18

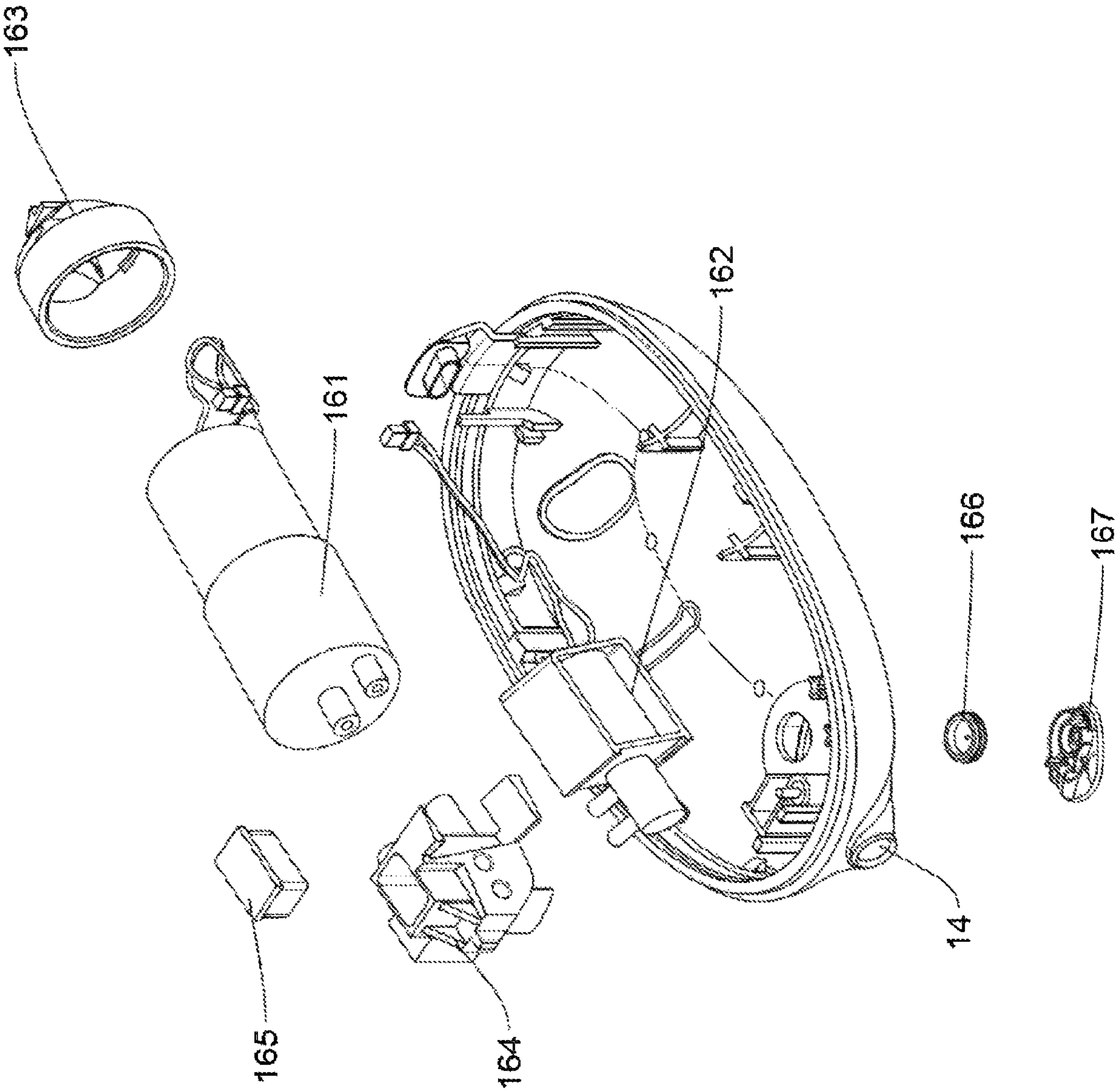


FIGURE 19

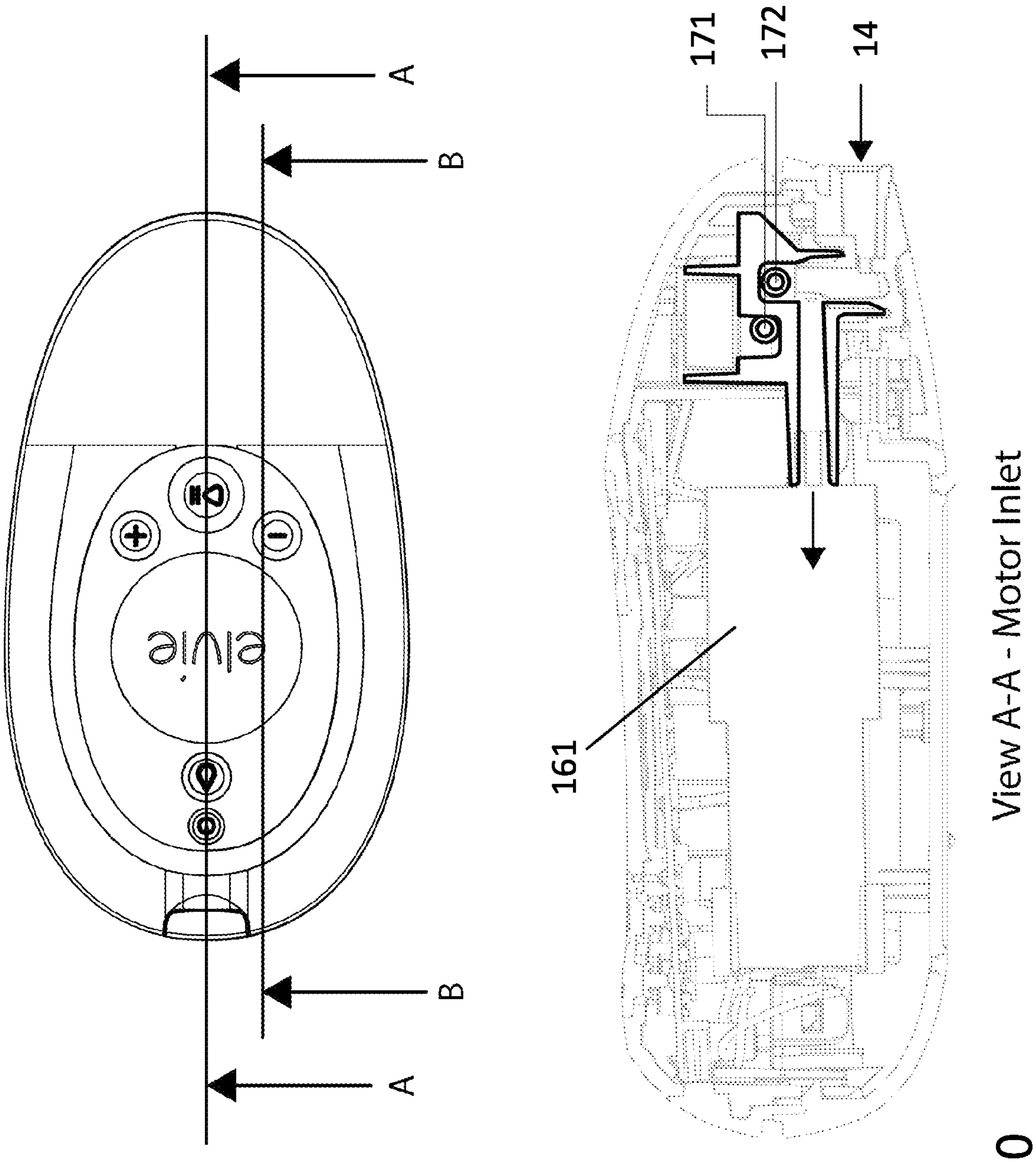
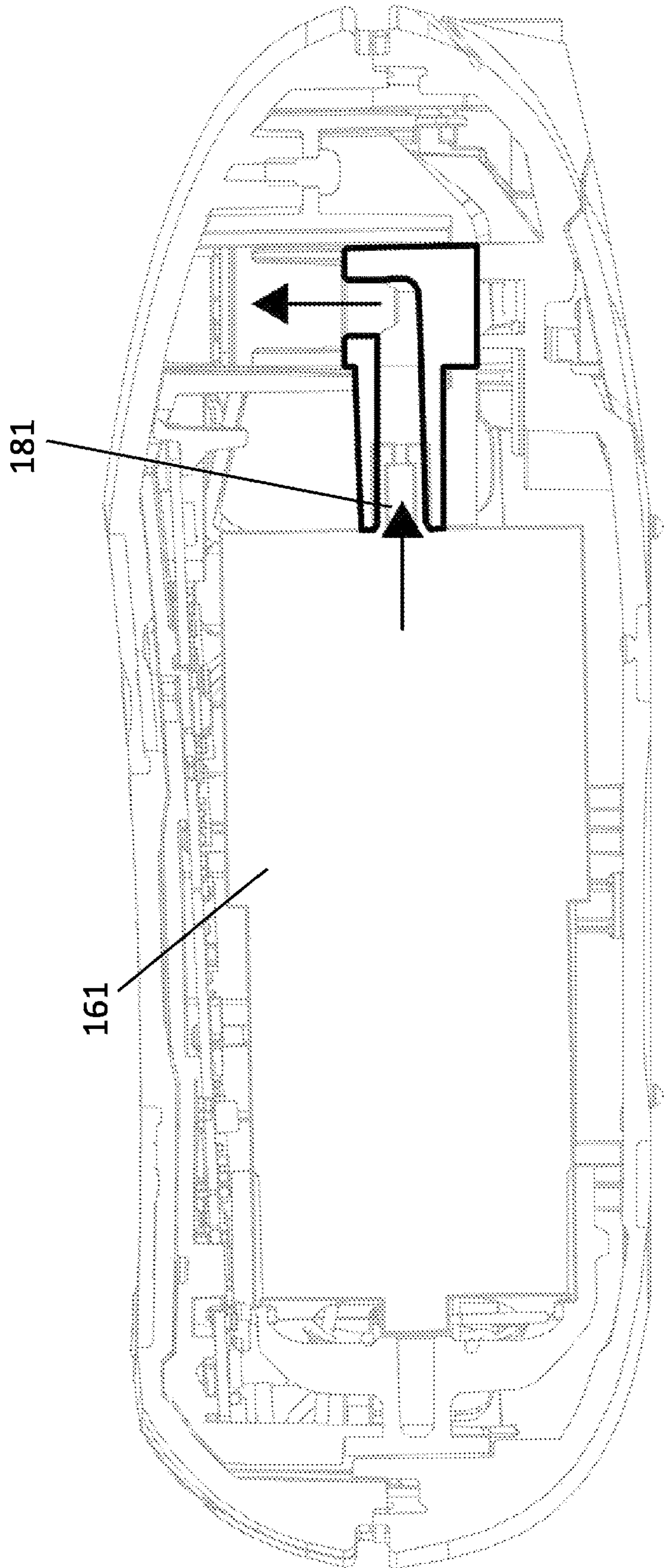


FIGURE 20



View B-B - Motor exhaust

FIGURE 21

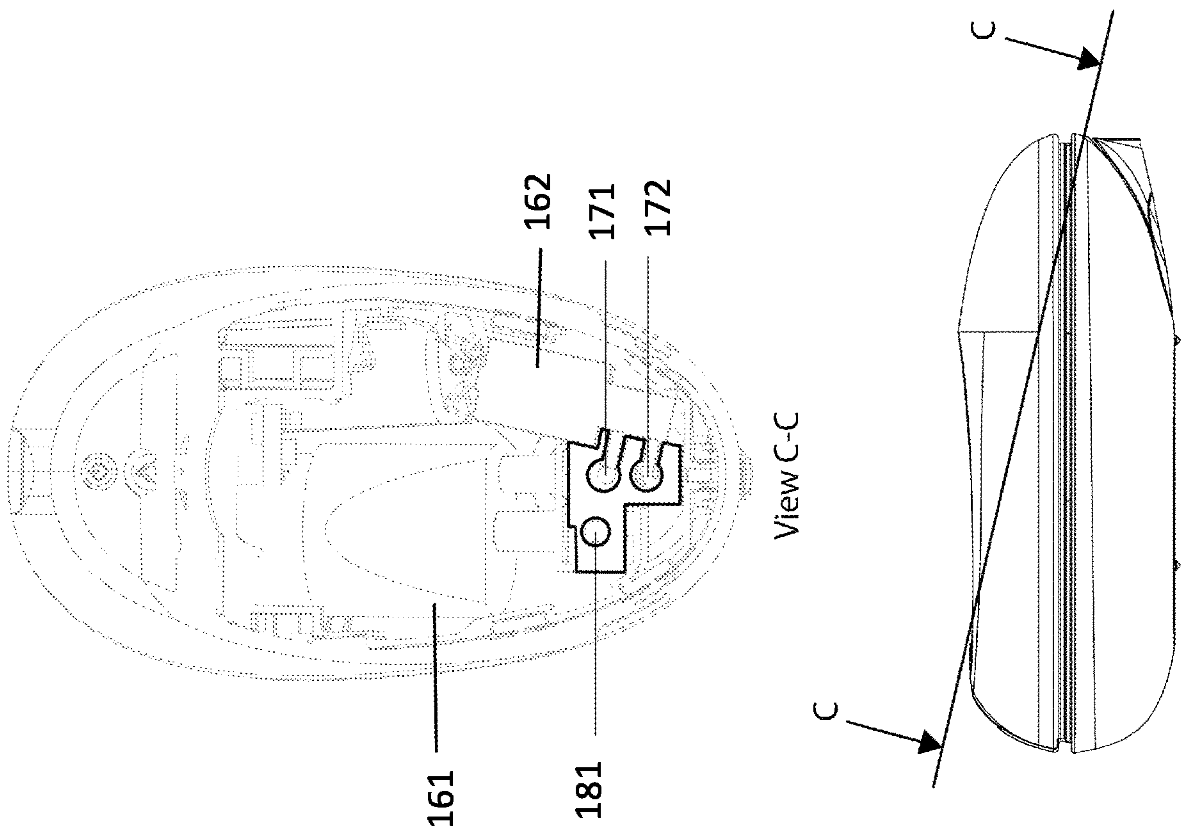


FIGURE 22

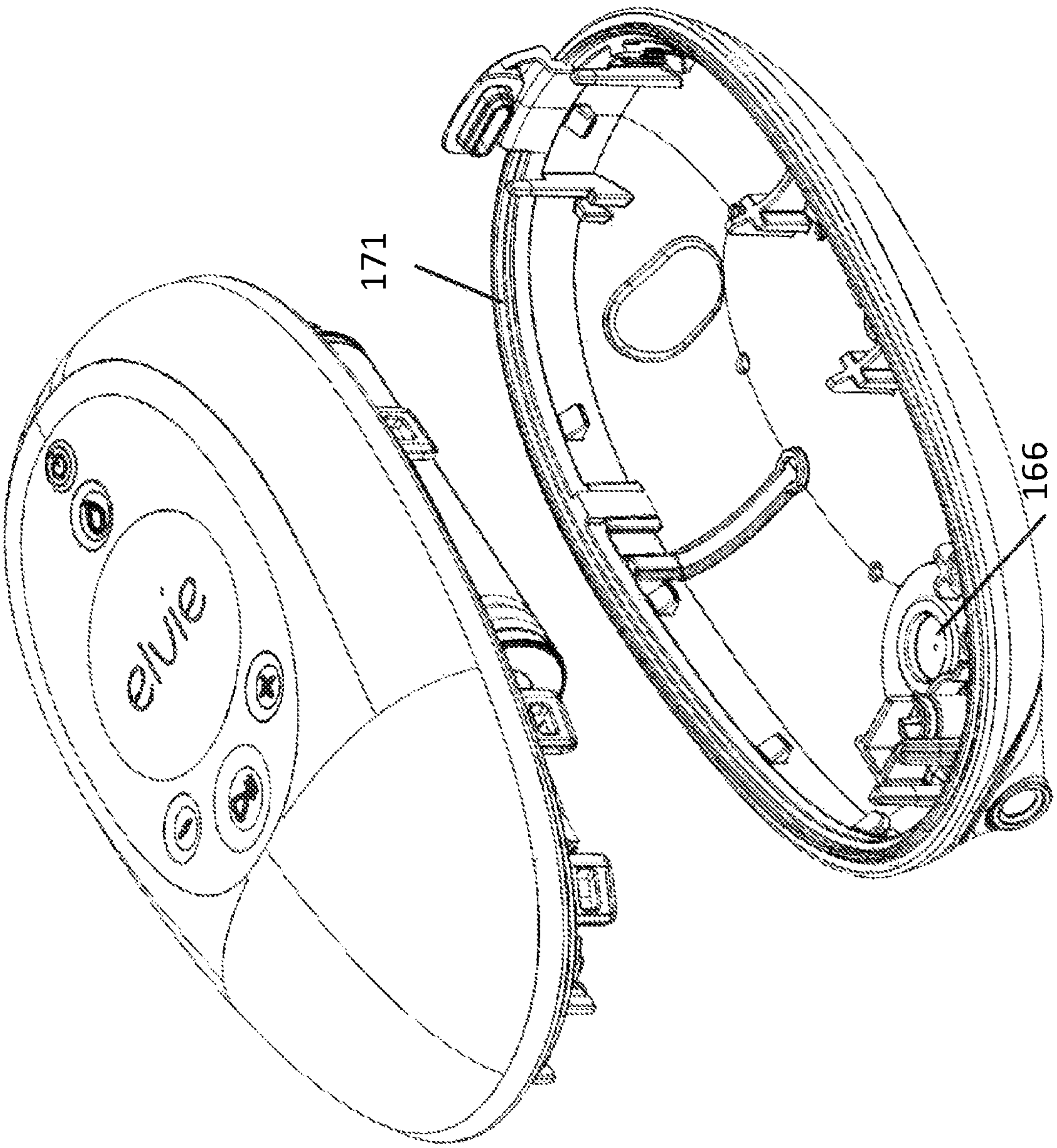


FIGURE 23

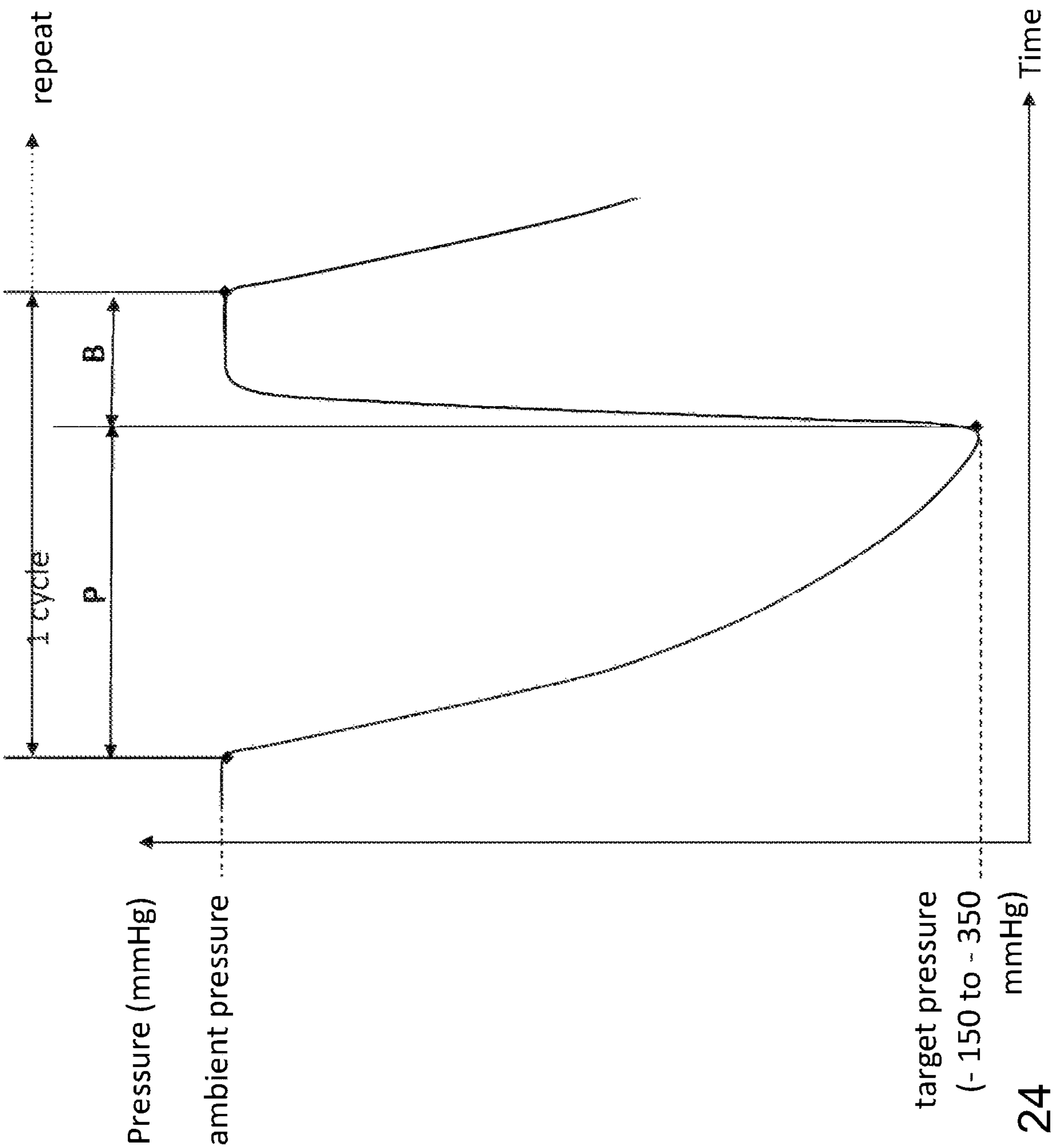

repeat
Time
1 cycle
P
B
Pressure (mmHg)
ambient pressure
target pressure
(- 150 to - 350
mmHg)

FIGURE 24

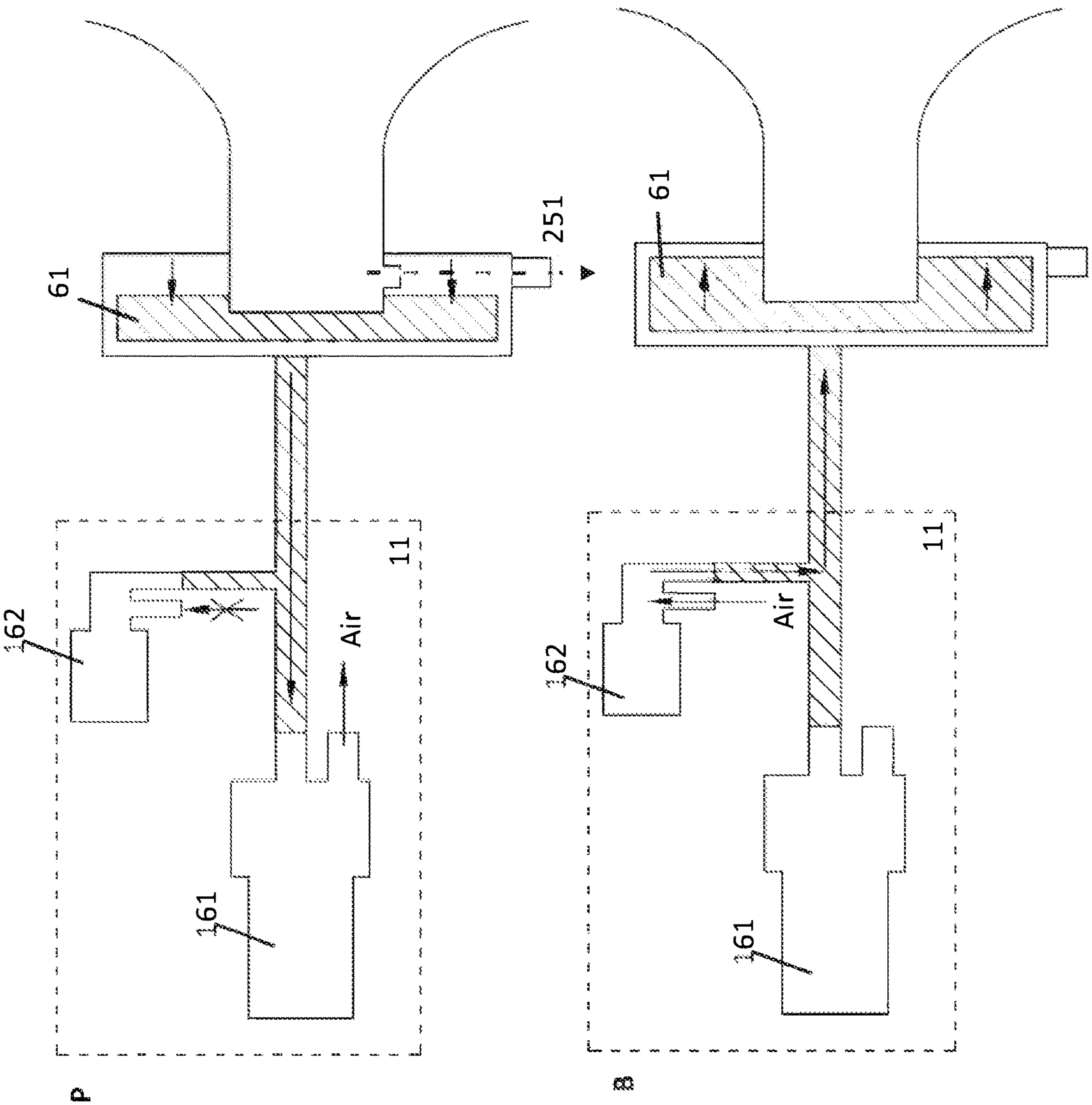


FIGURE 25

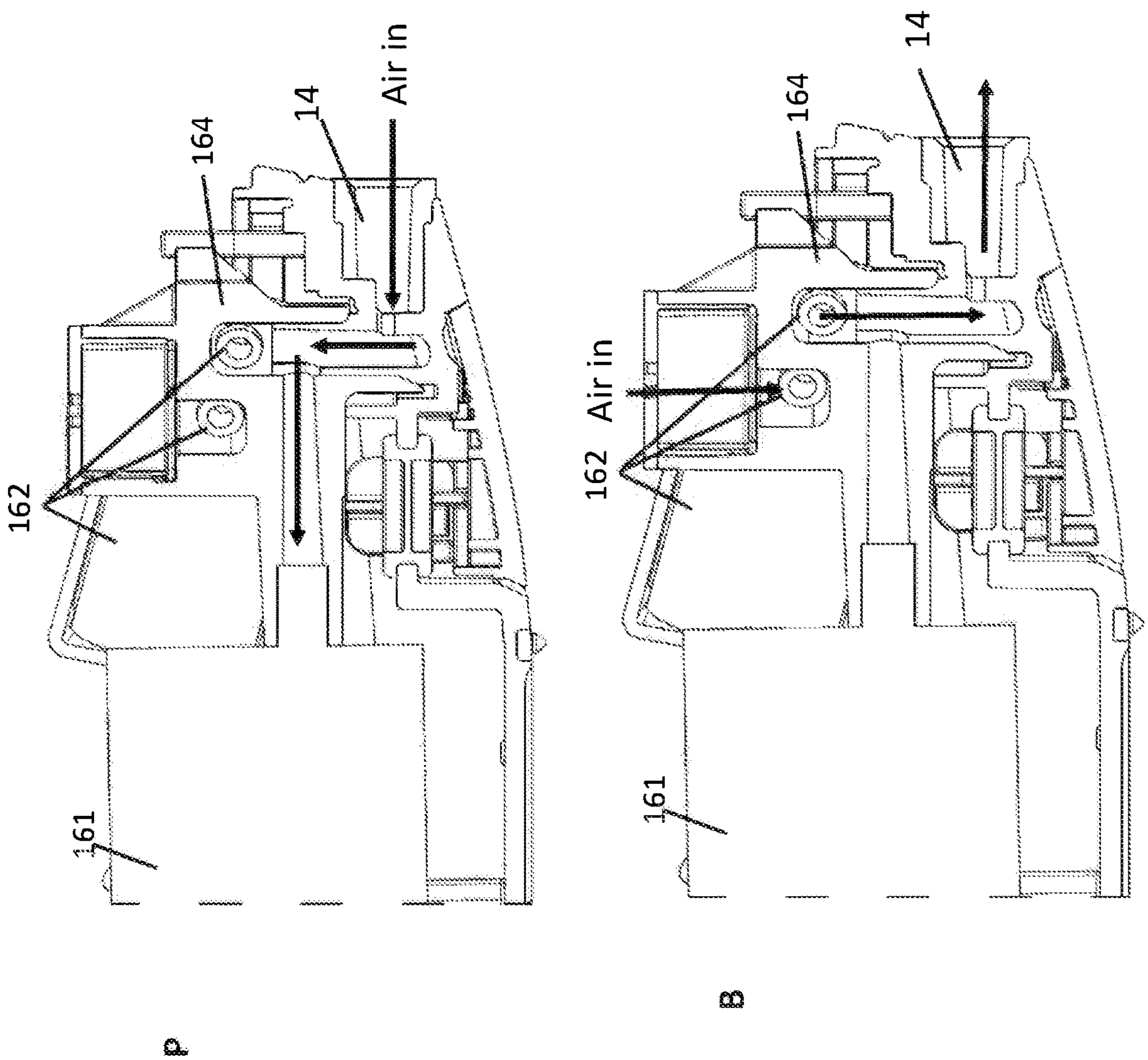
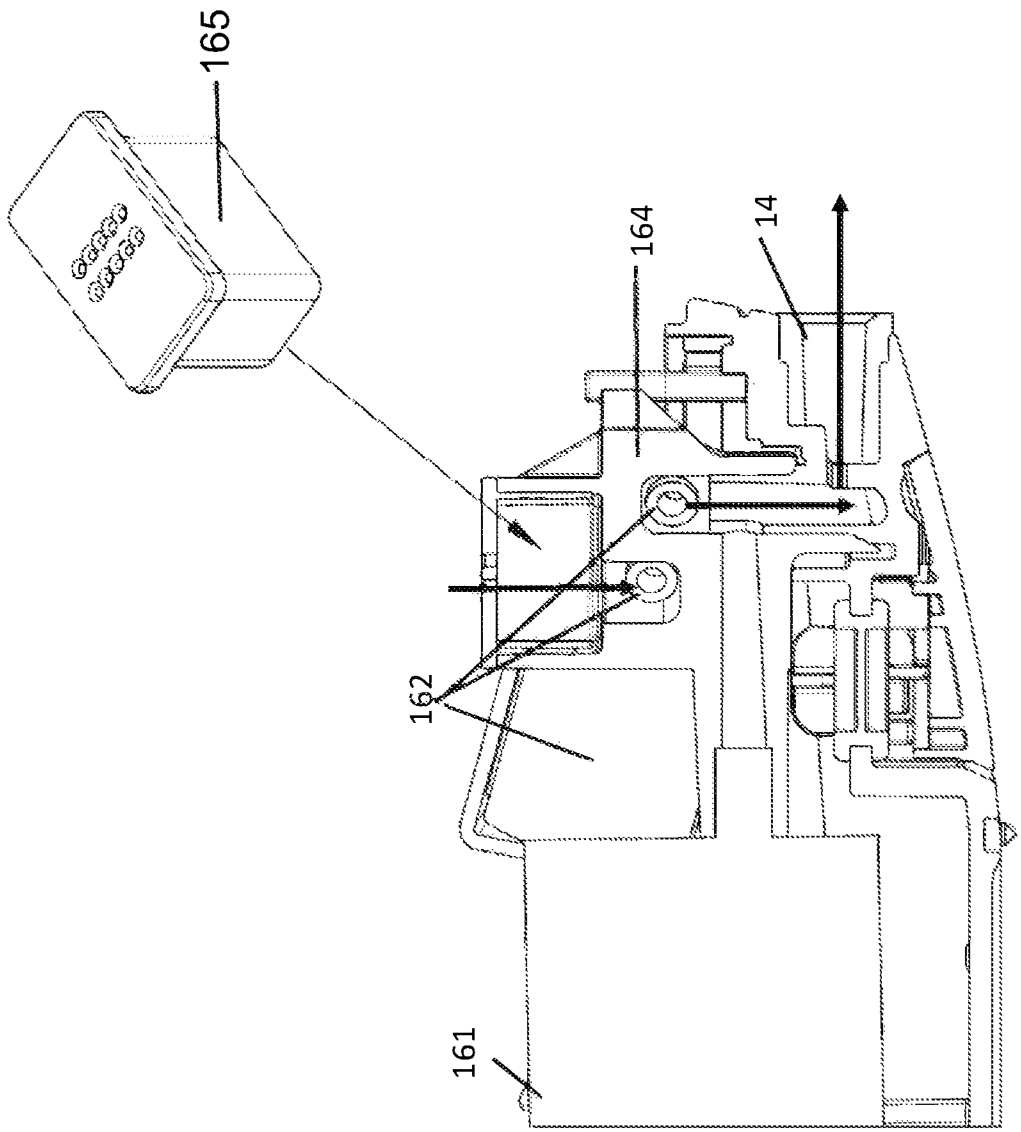


FIGURE 26



B

FIGURE 27

	Lima Single Profile	Lima Double Profile	Power Motor
STIMULATION			
Level 1	-60	-35	45%
Level 2	-85	-55	50%
Level 3	-105	-65	50%
Level 4	-115	-70	55%
Level 5	-135	-85	60%
Level 6	-170	-110	65%
Level 7	-190	-125	65%
Level 8	-210	-140	70%
level 9	-230	-155	70%
level 10	-250	-170	70%
EXPRESSION			
Level 1	-60	-35	45%
Level 2	-90	-55	50%
Level 3	-130	-80	60%
Level 4	-170	-110	65%
Level 5	-200	-130	65%
Level 6	-240	-160	70%
Level 7	-275	-190	73%
Level 8	-310	-220	75%
level 9	-340	-260	80%
level 10	-365/350	-300	80%

FIGURE 28

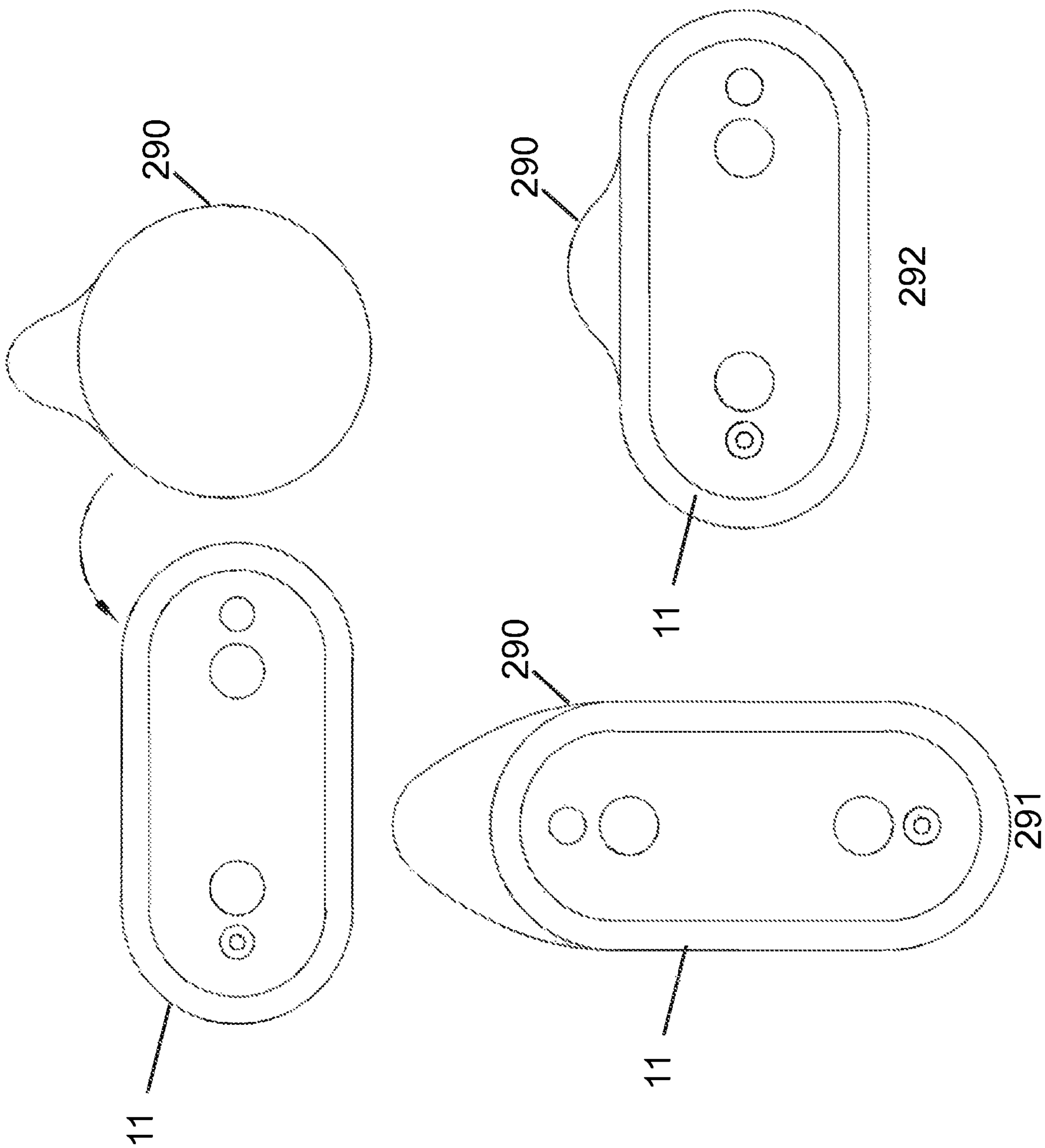


FIGURE 29

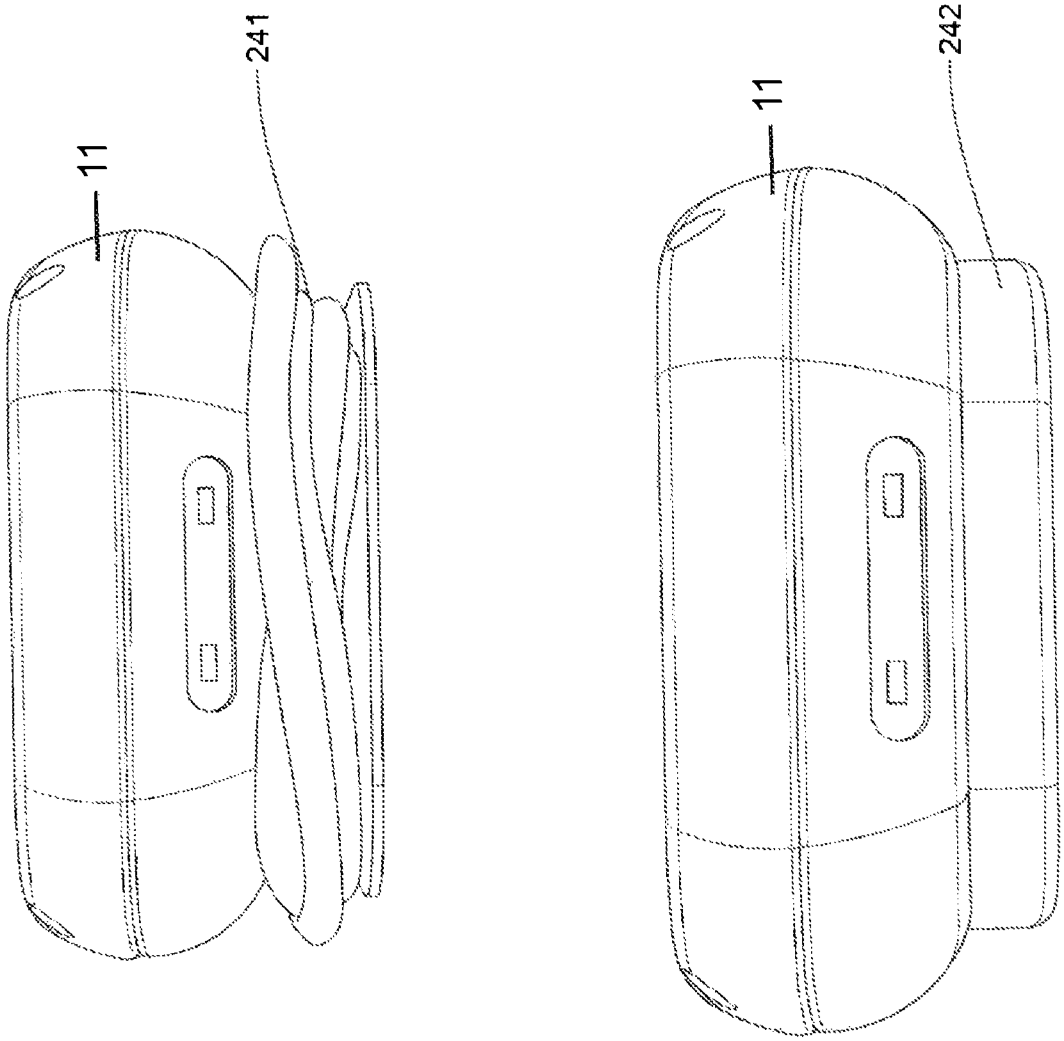


FIGURE 30

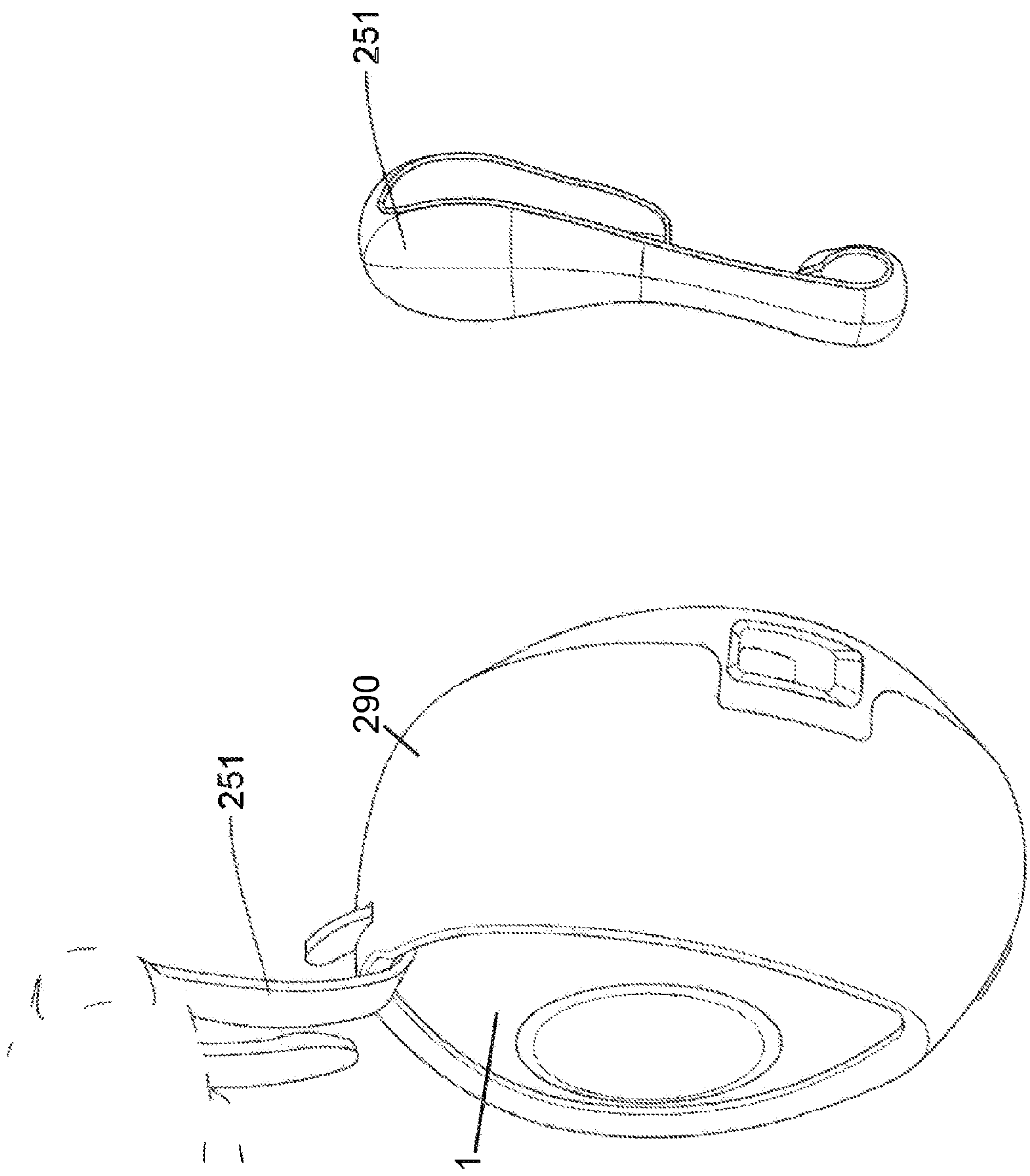


FIGURE 31

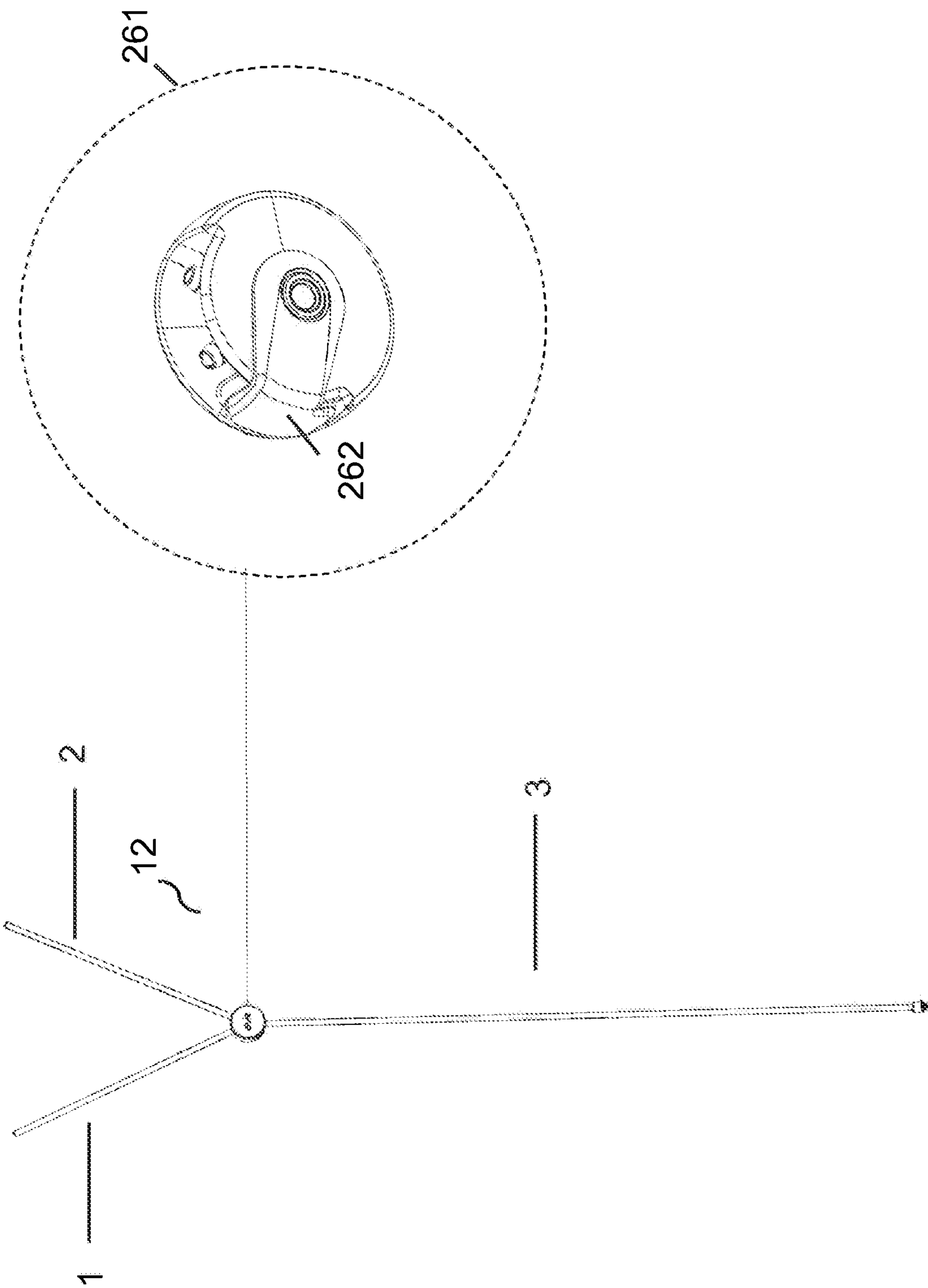


Figure 32

WEARABLE BREAST PUMP SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of U.S. application Ser. No. 17/907,347, filed Sep. 26, 2022, which is the national stage of International Application No. PCT/GB2021/050764, filed Mar. 26, 2021, which claims priority to GB Application No. 2004395.6, filed Mar. 26, 2020, each of which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a wearable breast pump system.

2. Description of the Prior Art

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

Most portable breast pump solutions that include a discreet design are not readily affordable for most parents. There is a need for a design of a wearable breast pump system with a sleek and discreet design as well as a lower price point.

A fully integrated wearable breast pump system is described in WO2018229504A1. The wearable breast pump system includes a housing shaped to fit inside a bra. The housing includes an air-pump that drives a diaphragm to generate negative air pressure. The diaphragm is seated on a diaphragm holder that is positioned away from a side of a breast shield flange.

A compact and hands-free human breast milk collection device that fits into a mother's existing nursing or standard brassiere is shown in the system of US20080262420A1. The hands-free collection device connects to an external regular pump via a vacuum hose that is also configured to apply a vacuum pressure to the internal volume of the collection device. The vacuum hose attaches to a stem located at a fixed position on the top exterior surface of the collection device. The position of the stem is chosen so that the pump will not suction breast milk into the external pump. Because it would be inconvenient and difficult to connect the vacuum hose to the stem located at the top of the device after the device has been placed on the breast, the vacuum hose has to be properly connected to the stem before the milk collection device is being placed on the breast.

A breast milk collection device is also shown in the system of US20180008758A1. The collection device attaches to a vacuum tube via an opening also located at a fixed position on the rim of the exterior surface of the collection device. The opening communicates with an interior chamber including an inflatable/deflatable flexible barrier that allows vacuum pressure to be applied to a breast. The flexible barrier housing that encloses the flexible barrier has an oval cone like shape and is located at the top of the collection device. Disadvantageously, the position of the flexible barrier obstructs the line of sight to the interior of the collection device and to the nipple.

Wearable hands free breast pumps have entered the market, such as the Freemie cups system. The Freemie cup includes a flexible barrier that sits on top of the cup, thereby obstructing the view of the interior of the cup and of the

nipple. Further, the cup is also made of a fairly opaque material, making it difficult to have a clear view of the interior of the device and of the nipple and to achieve a correct nipple alignment.

In view of the above, there is a need for an improved way to provide an easy and flexible connection between a suction tube and a wearable milk collection device. There is also a need to provide an unobstructed view of the interior chamber of the wearable milk collection device, in order to achieve a correct nipple alignment and to ensure the system is properly operating, such that milk is entering the interior of the device.

SUMMARY OF THE INVENTION

The invention is a breast pump system comprising at least one wearable milk collection hub connected via an air line to a combined external air pump and control unit. The milk collection hub(s) each comprise: a breast shield made up of a breast flange and a nipple tunnel; a flexible diaphragm that is configured to prevent milk from reaching the external air pump; an outer shell that is removably attachable to the breast shield, such that the breast shield and outer shell, when attached, form a vessel for collecting milk, and the front face of the outer shell includes a curved portion; a diaphragm cap that is configured to be secured over the diaphragm, and forms part of the front face or forward facing part of the outer shell, and includes a port connected to the air line.

This arrangement enables the air line to be connected to the front face of the outer shell of the milk collection hub; prior art devices position the diaphragm and air line on the top of the milk collection hub, which obscures the users view down into device, which in turn makes correct nipple positioning difficult. By having a diaphragm cap that forms part of the front face of the outer shell, the user's view down into the device is not obscured by a diaphragm that sits over the nipple; correct nipple positioning is easier to achieve.

In one implementation, the diaphragm cap can be rotated against the outer shell to adjust the position of the air port and hence the position and direction of the port and the air line connected to the port; this enables the user to readily adjust the position of the air line so that it lies comfortably under a bra or other clothing. The diaphragm cap may also be removable from the outer shell; then, the user can place the hub on the breast without the diaphragm cap, and without the inconvenience of an air line connected to the air port. Once a proper nipple alignment is achieved, the diaphragm cap and connected air line can then easily be attached back onto the outer shell of the milk collection hub.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of a wearable breast pump system that implements the invention:

FIG. **1**A shows a wearable breast pump system, made up of a pair of milk collection hubs, an air line and a separate combined control and air pump unit that is external to the milk collection hubs.

FIG. **1**B shows the wearable breast pump system with the milk collection hubs connected via the air line to the combined control and air pump unit.

FIG. **2** shows a perspective front view of a milk collection hub.

FIG. 3 shows a perspective rear view of a milk collection hub.

FIG. 4 shows a back view of the milk collection hub.

FIG. 5 shows a perspective view of the milk collection hub without the outer shell and without the diaphragm.

FIG. 6 shows an exploded view of the milk collection hub.

FIG. 7 shows the diaphragm.

FIG. 8 shows a cross section of a milk collection hub in a relaxed state.

FIG. 9 shows a cross section of a milk collection hub showing the diaphragm under maximum negative pressure.

FIG. 10 shows a perspective view of the removable diaphragm cap without the air tube.

FIG. 11 shows a front view of the removable diaphragm cap connected to the air tube.

FIG. 12 shows a perspective view of the removable diaphragm cap including the rigid pressure part.

FIG. 13A shows other cross section views of a milk collection hub in a relaxed state, at mid point and under maximum negative pressure.

FIG. 13B shows other cross section views of a milk collection hub including the milk port in a relaxed state, at mid point and under maximum negative pressure.

FIG. 14 shows a perspective view of the outer shell, without the removable diaphragm cap.

FIG. 15 shows a side view of a milk collection hub.

FIG. 16 shows a top down view of the control and air pump unit for the breast pump system.

FIG. 17 shows a top down view of the control and air pump unit, with the upper case of the unit removed.

FIG. 18 shows an exploded view of the control and air pump unit.

FIG. 19 shows the components of the pump unit subsystem.

FIG. 20 shows a cross section of the airflow block inside the control unit.

FIG. 21 shows a cross section of the airflow block inside the control unit.

FIG. 22 shows a cross section of the airflow block inside the control unit.

FIG. 23 shows the sound valve.

FIG. 24 shows a plot of the pumping cycle.

FIG. 25 shows schematics of the pump unit subsystem illustrating the pumping cycle.

FIG. 26 shows cross-sections of the control unit including the pump unit subsystem illustrating the pumping cycle.

FIG. 27 shows a cross section of the control unit including pump unit subsystem.

FIG. 28 shows a table listing different examples of vacuum levels.

FIG. 29 shows diagrams of a control unit including a multifunction mount.

FIG. 30 shows pictures of a control unit including accessories.

FIG. 31 shows diagrams of a control unit including a multifunction mount.

FIG. 32 shows the tube connection.

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-continued

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DETAILED DESCRIPTION

An implementation of the invention is a breast pump system for extracting and collecting breast milk. The system comprises a pair of milk collection hubs **10**, a combined control and air pump unit **11**, and an air tube connection component **12**, as shown in FIG. **1**A. In normal use, as shown in FIG. **1**B, air tubes **1**, **2** connect each milk collection hub **10** to the air tube connection component **12**; the air tube connection component **12** connects air tubes **1**, **2** to a single air tube **3**, that in turn leads to the control and air pump unit **11**.

The milk collection hubs may also be connected to any external control and air pump unit, including any external regular electric or manual control and air pump unit.

An intended use case involves the user placing either one or two milk collection hubs **10** onto their breast(s), connecting one or both collection hubs to the combined control and air pump unit **11** via the air tubes **1**, **2** and **3** and the tube connection component **12**.

The user controls the device using a user interface **13** located on the control unit **11**. Starting the breast pump system, via the user interface **13**, activates an air suction pump within the control and air pump unit **11** (also referred as control unit). An air port or hole **14** on the control and air pump unit **11** connects to a tube **3** which splits via a tube splitter in the air tube connection component **12** into two tubes **1**, **2**, which then deliver suction to the milk collection hubs **10** via air ports or holes **15** in each milk collection hub **10**. When the pump in unit **11** is activated, negative air pressure is created between the control unit **11** and the milk collection hub(s) **10**, thereby applying negative pressure to the nipple, drawing milk from the breast, and collecting it inside the milk collection hubs **10**.

The breast pump system can be operated using either one (single pumping) or two (double pumping) milk collection hubs **10**. The breast pump system can generate pressures in the range of 150 to 350 mmHg depending on the level of stimulation selected by the user.

FIGS. **2** and **3** show perspective views of a milk collection hub. The milk collection hubs **10** are both identical and are configured to be discreet and to be comfortably held inside a bra, with the outer shell **20** having a curved shape that is configured to contact the inner surface of the bra. The outer shell **20** fits or latches onto a breast shield **21** that forms the rear surface of the hub **10**. The breast shield **21** is made up of a breast flange **32** and a nipple tunnel **31**; the interior volume between the outer shell **20** and the breast shield **21** defines a chamber in which milk is collected. The breast flange **32** contacts the user's breasts. The outer shell **20** is directly removable from the breast shield in normal use or normal dis-assembly to enable cleaning of the interior volume in which milk is collected.

The outer shell **20** also includes a removable diaphragm cap **22** that covers and seals a diaphragm located inside the milk collection hub. The diaphragm cap **22** is located at the front of the outer shell **20**, and forms a central region on the front surface of the outer shell **20**. The diaphragm cap **22** includes the air port or hole **15** which provides the air connection to the control unit **11** via a tube. Because the diaphragm cap **22** is positioned at the front of the outer shell **20**, it does not block the user's view down through the transparent outer shell **20** into the interior of the milk collection hub; it hence enables the user to see whether the collection hub **10** is correctly positioned on a breast and whether milk is being successfully expressed into the collection hub **10**.

The diaphragm cap **22** is easily removable with one hand from the outer shell **20** of the hub in normal use or normal disassembly. Because the air line **1**, **2** is connected to the air hole **15** in the diaphragm cap **22**, removing the diaphragm cap **22** from the outer shell **20** provides a robust, easy, quick release of the suction connection between the hub **10** and the control unit **11**, and, similarly, a robust, easy, quick installation of the suction connection between the hub **10** and the control unit **11**. Generally, air lines **1**, **2** remain fixed to their respective diaphragm cap **22**, so the user does not have to worry about the potentially difficult process of attaching the air lines to the air port **15** in each collection hub **10**.

The removable diaphragm cap **22** can be rotated against outer shell **20** to adjust the position of the air port on the outer shell and hence the position and direction of the air lines **1**, **2**; this enables the user to readily adjust the position of the air lines **1**, **2** so that they lie comfortably under a bra or other clothing. The user can place the hub **10** on the breast without the diaphragm cap and without the inconvenience of an air tube **1**, **2** connected to the air port **15**. Once a proper nipple alignment is achieved, the diaphragm cap **22** and connected tube can easily be attached on the hub **10**.

In FIG. **3**, the breast shield **21** includes a nipple tunnel **31** shaped to receive a nipple and a flange **32**. Preferably, the breast shield **21** including the flange **32** and the nipple tunnel **31** is a single piece item made of a single moulding with a single smooth internal surface. There are no joins along the nipple tunnel; joins may aggravate the delicate nipple tissue as the nipple extends and contracts during pumping.

The breast shield **21** may be configured to slide onto the outer shell using a single push action. The breast shield **21** and outer shell **20** may also attach using magnets.

Preferably, the breast shield **21**, and the outer shell **20** and the diaphragm cap **22** are all substantially rigid and optically clear or substantially transparent, e.g. in order to provide an unobstructed view of the nipple and the inside of the hub **10**. The breast shield **21**, the diaphragm cap **22** and the outer shell **20** may for example all be made substantially of clear, rigid, dishwasher-safe material such as polypropylene, or a polycarbonate, or a co-polyester like Tritan™, or include sections of those materials sufficient to enable the user to clearly see inside the milk collection hub **10**. Being dishwasher-safe is important as it enables these components to all be easily cleaned in a normal dish-washing cycle. This also allows different components of the wearable breast pump system to be easily washed and/or sterilised. This rigidity and transparency helps achieve correct nipple alignment when placing the entire milk collection hub **10** onto the breast, as well as to enable the user to readily check whether the alignment is maintained while pumping. Milk collection hubs made of very flexible silicone can be harder to correctly position on breast. The nipple tunnel is also clearly visible to the user through the substantially transparent walls of the hub **10**, further ensuring that the spacing between the nipple and the side walls of the nipple tunnel **31** is correctly maintained while pumping.

During a pumping session, the user is also able to view the inside of the milk collection hub **10** and is able to ensure milk is being expressed inside the hub **10** and have an indication of the level of collected milk inside the hub. A scale **24** located on the outer shell **20** indicates the volume of milk inside the hub **10**.

The breast shield **21** may also include guide lines **33** running parallel to the sides of the breast shield in order to help with nipple alignment; these guide lines **33** are designed to be positioned generally horizontally in use, and to be easily seen by the user when looking down at the breast

shield **21** when positioned on breast; the lines enable the user to correctly position the breast shield **21** so that the nipple is positioned generally along the centre-line leading through the nipple tunnel (e.g. central axis **81** shown in FIG. **8**).

The outer shell also includes a milk pouring opening which can be closed using a removable part **23** to cover the milk pouring opening during pumping and general handling.

The breast shield **21** and/or outer shell **20** may be made of a substantially rigid polypropylene material, or a polycarbonate or a co-polyester material such as the Tritan material that is optically clear and dishwasher safe. The material may be particularly chosen as a balance of cost and acceptable achievable transparency.

FIG. **4** shows a back view of the milk collection hub. As shown, the nipple tunnel **31** includes a milk hole **41** through which expressed milk flows onto the milk collection hub. Guide lines **33** are positioned above the central axis of the nipple tunnel **31** and are not aligned with that central axis; this compensates for the slight parallax arising when viewing the guide lines **33** and nipple from above.

FIG. **5** shows a perspective view of the one-piece, rigid breast shield **21** but without the outer shell and without the diaphragm. Breast shield **21** includes an annular diaphragm housing **53**; diaphragm housing **53** has an outer, approximately cylindrical side wall **55** that is generally parallel to the nipple tunnel **31**, and a generally concentric, approximately cylindrical inner side wall **56** that forms the outer wall of the nipple tunnel **31**. Diaphragm housing **53** has a front wall **57** that forms the end of the nipple tunnel; it also has an annular rear wall **54** that joins the concentric inner wall **56** and the outer wall **55**.

FIG. **8** provides a cross-section showing these features. A flexible membrane **61** (see FIGS. **6-9** and FIGS. **13**A and **13**B) sits flush against these walls of the annular diaphragm housing **53** in the relaxed state (i.e. when no negative air pressure is applied) and hence has a similar shape, with a generally cylindrical outer membrane wall **64** that sits flush against housing cylindrical outer wall **55**; a concentric inner membrane wall **65** that sits flush against housing cylindrical inner wall **56**; a front wall **66** that sits over the end of the housing front wall **57** that forms the end of the nipple tunnel; and an annular rear wall **63** that sits flush against the diaphragm housing rear wall **54**.

Diaphragm cap **22** sits over the flexible diaphragm or membrane **61** and a negative pressure chamber is hence formed between diaphragm cap **22** and one side of the flexible diaphragm **61**. The diaphragm **61** hence moves within an air-pump chamber formed on one side by the diaphragm housing **53** and on the other side by the diaphragm cap **22**; flexible diaphragm **61** is pulled forwards, along the direction of central axis **81**, moving through this negative pressure chamber when suction is applied. As the flexible diaphragm **61** is pulled forwards, it creates a low air pressure region on the other side of the flexible diaphragm **61**, i.e. the side between the flexible diaphragm **61** and the diaphragm housing **53**. This in turn reduces the air pressure inside the nipple tunnel **31**, since milk hole **41** in the nipple tunnel **31** ensures air pressure equivalence between the inside of the nipple tunnel **31** and the inside of the diaphragm housing **53**; the pressure reduction draws the nipple forward and causes milk to be expressed from the nipple. Milk passes through the milk hole **41** of the nipple tunnel **31**, and then passes through a second milk hole or opening **52** located on the diaphragm housing **53**, and then flows inside the collection hub via a non-return valve **51** that is mounted on the second milk hole or opening **52**. The non-return valve enables milk to pass into the milk container in one direction. Note that the diaphragm housing **53**, and hence the diaphragm **61**, is placed towards the end of the nipple tunnel **31**, away from the breast shield **21**. Diaphragm **61** in fact extends over the end of nipple tunnel **31**. This structure has the benefit of giving the user a clearer view down through the nipple tunnel **31** when positioning the nipple inside the nipple tunnel **31**: if the diaphragm housing **53** were closer to the breast shield **21**, then that view would be blocked. The downside however is that the milk collection hub **10** is not compact in the direction of the nipple tunnel and is shaped to fit inside an inner portion of a bra.

Preferably, the non-return valve is removable for easy cleaning.

When the outer shell **20** is fitted on the breast shield **21**, the collection hub forms a vessel in which milk is collected after it passes through the non-return valve with a capacity to collect approximately 5 fluid ounces (148 ml).

The hub also includes a vent hole located for example at the top of the outer shell such that atmospheric pressure is maintained inside the vessel, even during negative pressure cycles.

FIG. **6** shows an exploded view of the milk collection hub **10**. In this example, the wearable milk collection hub **10** comprises the following user-removable parts: the breast shield **21**, the outer shell **20**, the diaphragm **61** and the diaphragm cap **22**. The diaphragm cap **22** fits over with an air-tight seal to the flexible diaphragm **61**. An air tight seal between the breast shield **21** and outer shell **20** is provided by a removable seal member **62**.

The flexible diaphragm **61** may either be fully removable from the hub **10** or may form an integral part of the outer shell **20**. When it is removable, it push-fits into the outer shell **20**, forming an air and liquid tight seal. When it is an integral part of the outer shell, the flexible diaphragm **61** is typically laser welded at its single outer, circular edge, to a single, circular edge in the outer shell **20**.

As noted above, the breast shield **21** includes a diaphragm housing portion **53**, in which the flexible diaphragm **61**, can move in and out, when assembled. The diaphragm housing portion **53** includes an air hole that transfers negative air pressure to the nipple tunnel **31**; this may be the milk hole **41** in the nipple tunnel **31** or another hole (not shown). The diaphragm **61** flexes when negative air pressure is applied to it by the external air pump unit subsystem located in the control unit and transfers negative air-pressure to pull the breast and/or nipple against the breast shield and apply suction to the nipple, to cause milk to be expressed.

FIG. **7** shows the diaphragm **61** in side view and also perspective view. The diaphragm **61** is configured to prevent milk from reaching the pump unit housed inside the control unit **11**.

The overall dimensions of the diaphragm are about 77.3 mm in diameter and 24 mm in height (ie depth along the long axis **81** of the nipple tunnel). The volume of air displaced by the diaphragm when under maximum suction is approximately 17550 mm^3. Typical variants may have dimensions that are ±25% of these dimensions.

The shape of the diaphragm **61** is not a substantially flat or ridged, convex membrane, as for example found in the Elvie Pump. Instead, it has an outer, approximately cylindrical side wall **64** that is generally parallel to the nipple tunnel **31**, and an inner, approximately cylindrical side wall **65** that is also is generally parallel to the nipple tunnel **31**. Diaphragm **61** has a front wall **66** that caps the inner side wall **65** and lies over the end of the nipple tunnel **31**. It also has an annular rear wall **63** that joins the outer and the inner sides walls **64**, **65**.

FIG. **8** is a cross section of a breast **85** inserted inside a milk collection hub in a relaxed state, showing the diaphragm **61** in relation to the axis of the nipple tunnel **81**, milk port **41** and the pressure chamber **82**. The flexible diaphragm **61** includes outer side wall **64** and inner side wall **65**, which each substantially run parallel to the center axis of the nipple tunnel **81**, and some portions, which substantially run perpendicular to the center axis of the nipple tunnel **81**. As illustrated, the diaphragm **61** includes inner annular wall **63** and end cap wall **66** which are perpendicular to the centre axis **81**. Much of the flexible diaphragm **61** lies over milk port **41** and also to the right (i.e. away from the breast) of the milk port **41**. Milk collection hub **10** is therefore not designed to be compact in the direction of the axis of the nipple tunnel **81**. Further, inside the nipple tunnel, the entire volume or space to the right of the nipple and breast is subject to negative pressure; the negative pressure zone hence starts at the skin/air boundary and so flexible diaphragm **61** is entirely to the right (i.e. away from the breast) of the negative pressure zone that is adjacent to the breast. Again, this leads to milk collection hub **10** not being compact in the direction of the axis of the nipple tunnel **81**. But that compromise is necessary in order to give the user a clear view down through the clear material of the breast shield **21** nipple and outer shell **20** so that the nipple can be correctly positioned within nipple tunnel **31**: correct positioning is very important for comfort and also effective milk expression.

FIG. **9** is a cross section of the breast **85** inserted inside a milk collection hub showing the diaphragm **61** under maximum negative pressure. During a negative air pressure phase the flexible diaphragm **61** flexes and moves towards the right; even the rear wall **63** moves past the milk port **41**. The central section **66** of the diaphragm **61** is at all times located substantially to the right of (i.e. extending beyond) the end of the nipple tunnel **31**. During suction, the central section **66** also moves forward into a pair of chambers **84** in the diaphragm cap **22**; this additional movement of the diaphragm **61** contributes significantly to the suction achieved inside the nipple tunnel, and hence the milk pumping efficacy.

The diaphragm **61** and associated diaphragm cap **22** are also positioned at the front of the hub **10** so as not to obstruct the mother's view of the nipple when placing the collection hub **10** onto her breast.

FIG. **10** shows perspective views of the removable diaphragm cap **22**. The diaphragm cap **22** includes a pair of hollow or recessed finger grip features **30**, making it easily handled using only two fingers. The diaphragm cap **22** is easily rotated so as to adjust the position of the air port **15** and hence the position of air tube **1**, **2** (not shown) that would be connected to the air port **15**.

FIG. **11** shows a front view of the removable diaphragm cap **22** connected to an air tube **1**. The air tube **1** may pass through a passage way located at the center of the diaphragm cap **22**, providing an additional protection for the air tube **1** so that it is not, in use, easily pulled out, and so that the direction of the tube **1** conforms with the surface of the inner bra. The diaphragm cap **22** may also be configured to attach to the outer shell **20** by means of a latch system. The diaphragm cap **22** may latch into the outside shell when spring plungers, such as ball bearings **100** in the diaphragm cap, locate into small indents in the outer shell **20**. An audible and/or haptic feedback may confirm that the removable diaphragm cap **22** and air tube **1** are properly assembled.

FIG. **12** shows a side view of the removable diaphragm cap **22** including an additional rigid part **91**. The additional part **91** is removable from the diaphragm cap **22** and is also shown in isolation. Alternatively, the additional part **91** may be an integral part of the diaphragm cap **22**. Additional part **91** reduces the volume of the pump chamber and hence leads to an improved pumping efficiency.

FIG. **13**A shows cross sections of a breast **85** inserted in the milk collection hub **10** including the additional rigid part **91** located in the pressure chamber. FIG. **13**B shows similar cross sections of the milk collection hub, but without the nipple. Note that the nipple sizing is approximate and that there are considerable variations in nipple size and in how nipples extend when under suction. Note also that these device cross sections are just one example and commercially available devices may differ. Diaphragm **61** is positioned over the end of nipple tunnel **31** and extends beyond the milk port **41** in the direction of axis **81** for the reasons given earlier, namely to provide a clear view of the nipple in the clear nipple tunnel **31**. Cross sections illustrate the diaphragm **61** movements from a relaxed state **101**, to a mid-point **102** and finally under maximum suction **103**. The diaphragm **61** is shown in a relaxed state, in relation to the axis of the nipple tunnel **81**, milk port **41** and the pressure chamber. The rigid pressure chamber part **91** reduces the volume of air inside the pressure chamber by limiting the movement of the diaphragm **61** under negative pressure, for example by blocking the pair of chambers **84** in the diaphragm cap **22**. The central section **66** of the diaphragm **61** is at all times located substantially to the right of (i.e. extending beyond) the end of the nipple tunnel **31**. When suction is applied, the member **61** moves forward along the direction of the central axis **81** of the wearable hub through the negative pressure chamber, as shown in the mid-point illustration **102**. The diaphragm **61** becomes flush with the rear surface of the rigid pressure chamber part **91** when it is fully displaced under maximum negative pressure.

In this configuration, by minimizing the volume of air in the pressure chamber, a faster response time and faster cycle time is achieved for single and double pumping, as well as greater peak negative pressure. In one implementation, using single pumping, the minimum pressure is 50 mmHg at cycle time of 75 cycles/min, and the maximum pressure is 350 mmHg at cycle time 30 cycles/min. Using double pumping, the minimum pressure is 30 mmHg at cycle time of 75 cycles/min and the maximum pressure is 280 mmHg at cycle time 30 cycles/min.

FIG. **14** shows a perspective view of the outer shell **20** including the milk pouring opening **111**.

FIG. **15** shows a side view of a milk collection hub. The overall width dimension of the milk collection hub **10** along the central axis of the nipple tunnel is about 5.7 cm; it is not designed to be particularly thin or compact in the direction of the axial arrow and has a width dimension that is similar or greater than earlier breast collection hubs, such as the Playtex Embrace™. The milk collection hub **10** includes a flat portion **120** located on the diaphragm cap **22**, so that the entire milk collection hub **10** can rest on a flat surface with the breast shield **21** uppermost.

Alternatively, the milk collection hub **10** may also include a flat portion on the base of the outer shell **20** such that the entire milk collection hub **10** can rest on a flat surface with the milk opening **111** uppermost.

Control Unit

The control unit **11** is configured to generate negative air pressure for the breast pump system. The control unit **11** has

a discreet form and is shaped to comfortably fit in the palm of the hand and be readily gripped by a single hand.

The control unit **11** is shaped to fit inside a pocket (or even a bra). Preferably, the control unit is less than 120 mm in length, less than 70 mm in width and less than 45 mm in height. Preferably, the control unit is less than 0.2 kg.

A user interface **13**, provided on the control unit **11**, may include buttons, haptic feedback, sliders, any form of display, lights, or any other componentry necessary to control and indicate the use of the breast pump system. The user interface is configured to be intuitive and easy to use.

A particular example of the user interface **13** is provided in FIG. **16** showing the top view of the control unit **11**. A power on/off button **131** powers on or off the breast pump system. One button **132** switches the pumping profile, such as between stimulation or expression modes. The buttons **133** and **134** adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast(s). A dual function pump/pause button **130** is also provided for the user to interrupt the pumping process without turning the device off.

A visual indicator includes a series of LEDs **135** that change appearance, with more LEDs being illuminated, as the pressure generated by the pump increases. Another visual indicator includes an LED **136** that changes appearance when the pumping profile changes. For example, one color indicates stimulation and another color indicates expression. As another example, the LED is turned off to indicate stimulation and is on to indicate expression. Another visual indicator includes an LED **137** that indicates the battery status. For example, the color red indicates low battery; orange indicates that the battery is charging; while green indicates when the battery is fully charged.

The battery is a rechargeable battery which can be charged via USB. Hence the control unit includes a USB charging socket **138** for transferring power to a power charging circuit housed inside the control unit.

The information provided through the user interface may also be supplemented by or alternatively conveyed solely through haptic feedback. The user interface may also take the form of a touchscreen.

FIG. **17** shows the control unit with the upper case removed. The visual indicators **135 136** and **137** including LEDs are mounted or attached on the chassis **140**.

FIG. **18** shows an exploded view of the control unit U with some of the key internal elements. The outside surface of the control unit is made of an upper case **151** and a lower case **152**, which when assembled together are adapted to house, hold and protect the internal components of the control unit **11**.

The control unit **11** houses an air pump unit subsystem **154** for generating a negative pressure in the milk collection hub(s), as well as a battery **155** and control electronics on PCB **153**. The chassis **140** holds in place the main components such as the air pump unit **154**, the battery **155** and the PCB **153**. The chassis also includes the actuators between the user interface and the PCB switches.

The breast pump system has been configured to deliver quiet operation in normal use. In particular, the control unit has been configured to both reduce motor vibration and attenuate sound from the pump unit subsystem **154**.

The components of the pump unit subsystem **154** are shown in FIG. **19**. A pump unit **161**, including a pump driven from a motor, is configured to generate negative air pressure. The pump unit **161** is connected to a bleed valve, such as a solenoid valve **162** that is configured to reset the system to ambient pressure when the motor stops.

Reduction of Motor Vibration and Attenuation of Sound

The breast pump system is designed to be more discreet compared to available solutions with respect to volume and sharpness of noise. This is enabled by one or more of the following: reducing the sound generated by the pump unit **161**; soundproofing the control unit **11**; reducing the power of the pump unit **161**, reducing the bleed sound by slowing down the airflow speed during rapid return to ambient air pressure after each pumping cycle, and absorbing the vibration of the pump motor in the pump unit subsystem **154**.

The motor vibrations are reduced by holding the pump unit **161** in place between two silicone parts: a sound attenuating motor mount **163** and an airflow block **164**. The sound attenuating motor mount **163** holds the back of the pump motor and absorbs part of the vibration of the pump motor. The airflow block **164** includes an air port or hole for routing the airflow from the pump unit **161** to the tube connector **14** and also absorbs part of the vibration of the pump unit. By using the two silicone parts, the vibration transmitted to the hard plastic case **151**, **152** is greatly reduced and hence the unit is significantly quieter than other pumping units; a major advantage when discretion is sought, and to reduce disturbance to baby.

Both the sound attenuating motor mount **163** and the airflow block **164** are one-piece items made of either compression-moulded or ISR moulded silicone.

FIGS. **20** to **22** provide cross sections of the airflow block that illustrates the air paths inside the airflow block. The airflow block **164** is a multifunctional block that:

- routes or directs the airflow from the tube connector **14** or inlet to the pump unit **161** (see FIG. **20**).
- directs the air from the motor exhaust **181** to the atmosphere through a simple straight hollow tube with an exit path at one end (see FIG. **21**).
- provides the mounting for the solenoid valve inlet **171** and outlet **172** (see FIGS. **20** and **22**).
- provides an isolation barrier for motor vibrations.

The airflow block **164** therefore is configured to both attenuate sound and to reduce motor vibration.

A number of components may be used to further reduce the sound generated by the pump unit subsystem including, but not limited to:

- A solenoid foam cap **165** to reduce bleed flow as well as bleed sound.
- A sound valve **166** (as shown also in FIG. **23**) located in the lower portion of the case **152**. The sound valve **166** allows the internal pressure of the control unit **11** to remain at ambient pressure without high levels of sound escaping from the control unit **11**. A sound valve cap **167** is also used to protect the sound valve **166** from the external environment.
- Sealing the control unit **11** so as to further attenuate sound. For example, a seal member **173** (see FIG. **23**) is included in between the upper part **151** and lower part **152** of the case, around the periphery of the control unit **11**, hence allowing no air to escape from the control unit **11**, to reduce the pump unit **161** sounds from travelling outside the control unit **11**. Optionally, the airflow block **164** may also be integrated with a portion of the seal member **173**.
- Mufflers or silencers can also be used reduce the airborne noise emitted from air inlets and/or exhausts. One silencer can be connected to the solenoid **162** and another silencer can be connected to the pump motor.

The sound valve **166** located on the lower part **152** of the case is shown in FIGS. **19** and **23**. The sound valve **166** is a silicone part configured to deform under pressure. Hence

it allows the air to pass in and out of the control unit **11**, whilst significantly attenuating the motor and pump noise from travelling out of the control unit **11**. The sound valve **166** also ensures that the inside of the control unit **11** remains at ambient pressure and that the pump unit **161** is working in the right conditions.

The sound valve may include a small cross section cut.

The pumping cycle is now described in FIGS. **24** to **26**.

Once the system is activated, a pumping cycle begins: the air-pressure pump turns on and creates negative air pressure during a first phase of the pumping cycle, referred to as the pumping time (P). When negative air pressure is applied to the milk collection hubs **10**, the flexible diaphragm **61** flexes and negative air pressure is conveyed to the inside of the nipple tunnel **31**, to pull the breast and/or nipple, thus drawing milk **251** from the nipple. During this first phase of the pumping cycle (P), the air-pressure pump **161** is configured to be on for a pre-defined amount of time in order to provide a target negative air pressure. During this first phase, the solenoid valve **162** is configured to be turned off.

After the target negative air pressure has been reached, the air-pressure pump **161** turns off, and air is bled into the system via the solenoid valve **162** during the second phase of the pumping cycle referred to as bleed time (B). At the end of the bleed time, the system is therefore reset to ambient pressure.

During this second phase of the pumping cycle, the solenoid valve **162** opens to reset the pressure in the milk collection hubs **10** to ambient, which causes a rush of air into the solenoid valve **162** and generates a sound, such as a sharp, high frequency sound. As discussed above, using a solenoid foam cap **165**, as shown in FIG. **27**, reduces the rush of air entering the solenoid valve **162** and therefore reduces the overall sound generated by the solenoid valve **162**. The solenoid foam cap **165** includes one or more small openings or holes that are configured to reduce and control air speed when entering the solenoid valve **162**. The solenoid foam cap **165** may be a one-piece item made of plastic.

The pumping cycle may be programmed to follow different modes, such as a stimulation mode and an expression mode, by controlling the pumping time and the bleed time. The pumping cycle and/or modes may also be programmed to reach different vacuum levels.

Stimulation mode is configured to encourage milk flow and expression mode is configured to maximize pumping efficiency. Each mode contains a number of different vacuum levels, such as 10 different vacuum levels, which can be selected via the user interface on the control unit.

FIG. **28** lists an example of 10 different vacuum levels for stimulation and expression modes and for single and double pumping. This is one example and commercially available devices may differ. Adjusting the power delivered to the pump motor also reduces the sound generated by the system.

Hence a desired vacuum level and sound for a particular mode may be achieved by controlling the time of both phases of the pumping cycle and the power delivered to the pump motor.

The perimeter of the control unit has a complete seal **173** (see FIG. **23**), dramatically reducing the airborne noise leaving the unit. This seal creates a significantly quieter product for the user.

Overall, in operation, the noise level is less than 50 dB and preferably less than 45 dB.

A number of removable accessories may be used that attach to the control unit **11** to improve the user experience. These may include for example:

- a removable, auxiliary battery pack for increasing the length of time a user can pump for between charges.
- a tube wrap device that clips to the back of the control unit, allowing the user to neatly store the tubes by wrapping them. This may also allow the user to customise the length of their tubes during use.
- a belt clip that allows the user to attach the control unit to their clothing, wearing it on their waistline or elsewhere.
- a lanyard that clips to the control unit, allowing the user to wear the control unit by hanging it around their neck.

The attachment method for accessories may involve an O-ring style loop that stretches over the control unit in multiple positions, allowing a control unit to be mounted in either portrait or landscape orientation.

Accessories for the Control Unit

The control unit may also include a number of easily removable accessories.

FIG. **29** shows diagrams of a control unit **11** including a multifunction mount such as an O-ring **290**. The multifunction mount enables the control unit **11** to be easily held by the user's fingers in different modes, such as portrait **291** or landscape mode **292**.

FIG. **30** shows pictures of the control unit **11** including a tube wrap accessory **241** located under the bottom case of the control unit **11**, and of the control unit including a battery accessory **242** located under the bottom case of the control unit **11**, such as a battery pack.

FIG. **31** shows a picture of a control unit **11** including an o-ring **290** mount extending around a periphery of the control unit **11**. The mount including a removable waistband clip **261** enabling the control unit to be, for example, clipped to a belt or trousers.

Tube Connection

FIG. **32** shows the tube connection **12** including the tube splitter **261**. The tube splitter **12** in effect splits the air line **3** that comes from the combined control and air pump unit **11** into two separate air lines **1**, **2** that attach to the two milk collection hubs **10**. Tube splitter **12** attaches to one end of the air lines **1**, **2** that are connected at their other end to the air port **14** in each milk collection hub **10**. The tube splitter attaches to one end of the air line **3** that is connected at its other end to the combined control and air pump unit **11**. Tube splitter **12** includes a bung or stopper **262** that can be rotated in order to configure the breast pump system for single pumping or double pumping, by creating an air path that leads from air line **3** into either the left airline **1** or the right air line **2** to activate respectively just the left hub or the right hub; or it can create an air path that leads from air line **3** into both left airline **1** and also right air line **2**, for double pumping.

Application Running on a Connected Device

Pump system related data may be sent by the system to a connected smartphone or other computer device. The data may be further analysed by a data analysis subsystem. The data may also be displayed on an application running on the computing device.

The application may provide one or more of the following features:

- Discreet/Remote control of device, such as: play/pause, mode change, intensity setting change.
- Battery life indication.
- Session time and date tracking.
- Milk volume tracking.
- Integration with other devices, such as other breast pump system.

APPENDIX 1

Key features of the breast pump system are now generalized into the following categories:

A. User experience: Nipple Visibility

B. Cost Engineering: Simplicity

C. User Experience: Low Noise

D. User experience: Product Handling

Note that any feature can be combined with any one or more other features. The invention is however defined in the appended claims. Note further that, whilst the implementation described above is a breast pump system with one or two in-bra wearable milk collection hubs, each connected to an external air pump, it is possible to integrate an air pumping mechanism, rechargeable battery and control electronics inside each milk collection hub, in much the same way as the Elvie Pump (see WO 2018/229504) integrates an air pump, rechargeable battery and control electronics into an in-bra wearable unit that includes a user-attachable milk collection container. The following features do not, unless otherwise explicitly stated, require an external air pump, but should be expansively construed to cover breast pump systems that can utilise an external or internal air pump. Similarly, whilst the implementation described above is a breast pump system with a closed-loop air pump (i.e. the pump is protected from any possibility of milk contamination through the flexible membrane), the following features do not, unless otherwise explicitly stated, require a closed-loop air pump, but should be expansively construed to cover breast pump systems that are both closed loop and also open loop.

A. User Experience Innovations: Nipple Visibility

Feature 1: Visibility of the Nipple

One implementation of this invention envisages a wearable milk collection hub for a breast pump system that provides a clear and unobstructed view of the nipple for easy nipple alignment. This ensures that a correct alignment is maintained while pumping. The breast shield and outer shells are both substantially clear providing a clear and unobstructed view of the nipple when the assembled system is placed on the breast. This further enables the user to ensure proper nipple suction when the breast pump system is placed on the breast and while pumping.

We can generalize to:

A wearable milk collection hub for a breast pump system comprising:

(a) a breast shield made up of a breast flange and a nipple tunnel;

(b) a flexible diaphragm that is configured to prevent milk from reaching an external air pump subsystem;

(c) an outer shell that is configured to removably attach to the breast shield, such that the breast shield and outer shell form a vessel for collecting milk;

in which the breast shield and the outer shell are substantially transparent, providing, to the mother placing the collection hub onto her breast, a clear and unobstructed view of the nipple to facilitate correct nipple alignment.

Feature 2: Visibility of the Nipple and of the Flexible Diaphragm

In addition to the clear and unobstructed view of the nipple, the system also provides a clear and unobstructed view of the diaphragm inside the hub. A user is able to see any movement of the diaphragm while pumping and ensure the system is correctly operating. The diaphragm is placed so as not to obstruct the line of sight to the nipple, hence providing both a view of the nipple and of the flexible diaphragm.

We can generalize to:

A wearable milk collection hub for a breast pump system comprising:

(a) a breast shield made up of a breast flange and a nipple tunnel;

(b) a flexible diaphragm that is configured to prevent milk from reaching an external air pump subsystem;

(c) an outer shell that is configured to removably attach to the breast shield, such that the breast shield and outer shell form a vessel for collecting milk;

in which the breast shield and the outer shell are substantially transparent, providing simultaneously to the mother placing the collection hub onto her breast (i) a clear and unobstructed view of the nipple to facilitate correct nipple alignment and (ii) a view of the diaphragm to ensure the breast pump system is operating correctly.

Feature 3: Visibility of the Nipple and of a Substantial Part of Nipple Tunnel

The system is also able to provide an unobstructed view of the nipple tunnel for easy nipple alignment when the system is placed on the breast and while pumping. This further ensures that the spacing between the nipple and the side walls of the nipple tunnel is correctly positioned and maintained while pumping.

We can generalize to:

A wearable milk collection hub for a breast pump system comprising:

(a) a breast shield made up of a breast flange and a nipple tunnel;

(b) a flexible diaphragm that is configured to prevent milk from reaching an external air pump subsystem;

(c) an outer shell that is configured to removably attach to the breast shield, such that the breast shield and outer shell form a vessel for collecting milk;

in which the breast shield and the outer shell are substantially transparent, providing to the mother placing the collection hub onto her breast (i) a clear and unobstructed view of the nipple to facilitate correct nipple alignment and (ii) a clear and unobstructed view of a substantial part of the nipple tunnel.

Feature 4: Diaphragm is Removably Mounted.

The wearable milk collection hub also includes a removable diaphragm that is configured to separate the air pump side from the milk side located in the hub, and thus prevents any contamination of the air pump unit by any milk. The diaphragm is shaped so that it includes portions which are either substantially parallel to the center axis of the nipple tunnel or substantially perpendicular to the center axis of the nipple tunnel.

We can generalize to:

A wearable milk collection hub for a breast pump system comprising:

(a) a substantially transparent breast shield made up of a breast flange and a nipple tunnel;

(b) a flexible diaphragm that is configured to prevent milk from reaching an external air pump subsystem;

(c) a substantially transparent outer shell that is configured to removably attach to the breast shield, such that the breast shield and outer shell form a vessel for collecting milk;

in which the diaphragm is removably mounted onto the breast shield and/or the outer shell, and in which the diaphragm includes a portion that is arranged over the end or tip of the nipple tunnel.

Feature 5: Specific Shape and Location of the Diaphragm

The diaphragm is also positioned so that it does not obstruct a mother's view of the nipple when placing the

collection hub onto her breast. Hence a mother is able to see any movement of the diaphragm when the air pump is activated, thereby further ensuring the proper function of the breast pump system.

We can generalize to:

A wearable milk collection hub for a breast pump system comprising:

(a) a breast shield made up of a breast flange and a nipple tunnel;

(b) a flexible diaphragm that is configured to prevent milk from reaching an external air pump subsystem;

(c) an outer shell that is configured to removably attach to the breast shield, such that the breast shield and outer shell form a vessel for collecting milk;

in which the diaphragm is removably mounted onto the breast shield and/or the outer shell and is positioned behind a diaphragm cap that forms part of the front or forward facing part of the outer shell, so as not to obstruct a mother's view of the nipple when placing the collection hub onto her breast.

B. Cost Engineering Innovations: Simplicity

Feature 6: Removable Diaphragm Cap

The wearable milk collection hub includes a removable diaphragm cap that is configured to cover and seal the diaphragm. The diaphragm cap is easily removable or attachable with a single push action when the collection hub has been placed onto the breast. The diaphragm cap includes an air port or hole to connect a tube between the milk collection hub and an external control unit housing a pump unit subsystem.

Hence a mother can place the collection hub on her breast first without the diaphragm cap and without the inconvenience of a tube connected to the air port. Once the milk collection hub is correctly placed on the breast, the mother can easily attach the diaphragm cap together with the tube with a single push action.

We can generalize to:

A wearable milk collection hub for a breast pump system comprising:

(a) a breast shield made up of a breast flange and a nipple tunnel;

(b) a flexible diaphragm that is configured to prevent milk from reaching an external air pump subsystem;

(c) an outer shell that is configured to removably attach to the breast shield, such that the breast shield and outer shell form a vessel for collecting milk;

in which the outer shell includes a removable diaphragm cap that covers and seals the diaphragm; and in which the diaphragm cap forms part of the front or forward facing part of the outer shell and includes an air port configured to transfer negative air pressure from the external air pump subsystem to the diaphragm.

Feature 7: Removable Diaphragm Cap is Omnidirectional

A further advantage of the diaphragm cap is that it is omnidirectional and can be easily rotated on the rear surface of the outer shell, therefore providing the user with the ability to change or rotate the position of the air port on the diaphragm cap. This also helps the user modify the placement of a tube connected to the diaphragm cap. This feature also provides added versatility and/or flexibility to be used by different users and body shape with different clothing to achieve comfort and/or discretion.

We can generalize to:

A wearable milk collection hub for a breast pump system comprising:

(a) a breast shield made up of a breast flange and a nipple tunnel;

(b) a flexible diaphragm that is configured to prevent milk from reaching an external air pump subsystem;

(c) an outer shell that is configured to removably attach to the breast shield, such that the breast shield and outer shell form a vessel for collecting milk;

in which the outer shell includes a removable diaphragm cap that covers and seals the diaphragm; and in which the diaphragm cap forms part of the front or forward facing part of the outer shell and includes an air port configured to transfer negative air pressure from the external air pump subsystem to the diaphragm; and in which the removable diaphragm cap is configured to rotate to enable the position of the air port on the outer shell to be adjusted by a user.

Feature 8: 3 User-Removable Parts from the Breast Shield

We can generalize to:

A wearable milk collection hub for a breast pump system comprising:

(a) a breast shield made up of a breast flange and a nipple tunnel;

(b) a flexible diaphragm that is configured to prevent milk from reaching an external air pump subsystem;

(c) an outer shell that is configured to removably attach to the breast shield, such that the breast shield and outer shell form a vessel for collecting milk;

(d) a diaphragm cap that forms part of the front or forward facing part of the outer shell;

and in which the only user removable items from the breast shield are: the outer shell, the diaphragm, and the diaphragm cap, in normal use or normal disassembly.

C. User Experience Innovations: Low Noise

Feature 9: Airflow Block

We can generalize to:

A control unit for generating negative air pressure for a breast pump system, the control unit including:

(a) a rechargeable battery;

(b) a power charging circuit for controlling the charging of the rechargeable battery;

(c) control electronics powered by the rechargeable battery;

(d) a pump powered by the rechargeable battery and generating negative air pressure; and

(e) a motor for driving the pump;

(f) a casing;

in which the control unit further includes an airflow block that is configured to transfer suction from the pump to a suction or air port on the control unit and is further configured to attenuate sound from the pump and/or the motor reaching from reaching the casing.

Feature 10: Sound Valve

We can generalize to:

A control unit for generating negative air pressure for a breast pump system, the control unit including:

(a) a rechargeable battery;

(b) a power charging circuit for controlling the charging of the rechargeable battery;

(c) control electronics powered by the rechargeable battery;

(d) a pump powered by the rechargeable battery and generating negative air pressure; and

(e) a motor for driving the pump;

and in which the control unit further includes a sound valve that is configured to air to pass in and out of the control unit sufficient for pressure equalisation between the inside and outside of the control unit, while minimizing sound from the pump and/or motor escaping from the control unit.

Feature 11: Solenoid Foam Cap

We can generalize to:

A control unit for generating negative air pressure for a breast pump system, the control unit including:

(a) a rechargeable battery;

(b) a power charging circuit for controlling the charging of the rechargeable battery;

(c) control electronics powered by the rechargeable battery;

(d) a pump powered by the rechargeable battery and generating negative air pressure and;

(e) a motor for driving the pump;

(f) a solenoid valve for controlling the generated negative air pressure;

and in which the control unit further includes a cap or other structure that is configured to reduce the speed of air that enters the solenoid valve when the solenoid valve opens to ambient air pressure.

D. User Experience Innovations: Product Handling

Feature 12: Multifunction Mount

We can generalize to:

A control unit for generating negative air pressure for a breast pump system, the control unit including:

(a) a rechargeable battery;

(b) a power charging circuit for controlling the charging of the rechargeable battery;

(c) control electronics powered by the rechargeable battery;

(d) a pump powered by the rechargeable battery and generating negative air pressure and;

(e) a motor for driving the pump;

and in which the control unit further includes a removable multifunction mount configured to attach to the control unit in at least two different positions, such that the control unit can be held in either upright/portrait or longwise/landscape mode.

Feature 13: Tube Management Feature

We can generalize to:

A control unit for generating negative air pressure for a breast pump system, the control unit including:

(a) a rechargeable battery;

(b) a power charging circuit for controlling the charging of the rechargeable battery;

(c) control electronics powered by the rechargeable battery;

(d) a pump powered by the rechargeable battery and generating negative air pressure and;

(e) a motor for driving the pump;

and in which the control unit further includes or, is removably attached to a tube management structure configured to enable an air tube attachable to the control unit to be wound around that tube management structure.

Generally applicable optional features that can be combined with any one or more of the above features and can themselves be combined with one another:

Breast Shield

breast shield is rigid or semi-rigid.

breast shield is made up of a breast flange and a nipple tunnel; in which the nipple tunnel is configured to receive a nipple.

breast shield comes in different sizes, each of which are configured to attach to the same outer shell.

different sizes of the breast shield each provide a different spacing of the nipple from side walls of the nipple tunnel, when the breast shield is positioned onto a breast.

breast shield integrates the breast flange and nipple tunnel as a single one-piece item with no joins.

nipple tunnel includes a milk hole through which express milk flows into the milk collection hub via a non return valve.

breast shield includes a diaphragm housing that has sides that are parallel to the nipple tunnel.

diaphragm housing includes an air hole that transfers negative air pressure to the nipple tunnel.

air-pump chamber is a substantially annular chamber with walls that are parallel to the long or central axis of the nipple tunnel and those parallel walls lie over a region of the nipple tunnel that is subject in use to negative air pressure.

diaphragm housing has an outer, approximately cylindrical side wall that is generally parallel to the nipple tunnel, and an inner, approximately cylindrical side wall that is also is generally parallel to the nipple tunnel.

diaphragm housing has a front wall that forms the end of the nipple tunnel.

diaphragm housing has an annular rear wall that joins the outer and the inner sides walls and that annular rear wall lies over a region of the nipple tunnel that is subject in use to negative air pressure.

diaphragm moves within an air-pump chamber formed on one side by the diaphragm housing with walls that are parallel to the long or central axis of the nipple tunnel and on another side by the diaphragm cap.

breast shield is integrated with the diaphragm housing portion as a single, one piece moulded item.

breast shield includes a removable perimeter seal that provides an air-tight seal between an outer edge of the breast shield and the outer shell.

breast shield is a transparent or optically clear, dishwasher safe polypropylene, polycarbonate or copolyester, such as Tritan™, breast shield.

Outer Shell

outer shell is rigid.

the outer shell removably attaches, fits or latches onto the breast shield and so the breast shield provides a rear surface that is in contact with milk.

outer shell is attachable to the breast shield with a single push action.

outer shell attaches to the breast shield using magnets.

outer shell includes an air opening or vent hole such that atmospheric pressure is maintained inside the milk collection hub.

outer shell is directly removable from the breast shield in normal use or normal dis-assembly

outer shell is removable from the breast shield together with a flexible diaphragm that is attached, permanently or removably, to the outer shell.

outer shell is an integral part of the breast shield.

outer shell includes a diaphragm cap that sits over a diaphragm.

outer shell and diaphragm are together a single item.

outer shell includes a pouring opening which can be closed for transportation of the milk collection hub.

outer shell has a front surface that is curved to fit inside a bra and to contact the inner surface of the bra.

outer shell is a transparent or optically clear, dishwasher safe polypropylene, polycarbonate or copolyester, such as Tritan™, outer shell.

outer shell is a self-contained milk collection hub and so the breast shield does not provide a surface in contact with milk.

Diaphragm

diaphragm is flexible, and deforms to create negative pressure.

diaphragm is not sufficiently flexible to deform to create negative pressure but serves instead solely to prevent milk from passing through it and filling the air lines or reaching the motor.

diaphragm is substantially rigid and serves instead solely to prevent milk from passing through it and filling the air lines or reaching the motor.

diaphragm includes inner and outer side walls that are substantially parallel to the center axis of the nipple tunnel.

diaphragm includes substantially cylindrical inner and outer side walls that are substantially parallel to the center axis of the nipple tunnel.

diaphragm, when under negative pressure, moves past a milk opening in the nipple tunnel towards the over the end or tip of the nipple tunnel.

diaphragm includes portions which are substantially parallel to the center axis of the nipple tunnel and includes portions which are substantially perpendicular to the center axis of the nipple tunnel.

diaphragm is shaped to be flush to a diaphragm housing that has an outer, approximately cylindrical side wall that is generally parallel to the nipple tunnel, and an inner, approximately cylindrical concentric side wall that is also is generally parallel to the nipple tunnel.

diaphragm flexes when negative air pressure is applied to it by an air pump subsystem, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

diaphragm is positioned such as not to obstruct a mother's view of a substantial part of the nipple tunnel when placing the collection hub onto her breast;

diaphragm is moulded as part of, or otherwise attached to, the outer shell.

the outer shell and diaphragm are formed or joined together to form a single item.

diaphragm includes portions that run substantially parallel to the center axis of the nipple tunnel.

diaphragm is a single flexible membrane shaped to include inner and outer substantially cylindrical walls that are generally parallel to the center axis of the nipple tunnel.

diaphragm includes a portion that sits over the end of the nipple tunnel, facing away from the breast.

diaphragm is removably attached to the outer shell.

diaphragm is removable from the outer shell for cleaning

diaphragm is configured to self-seal under the negative air pressure to a

diaphragm holder that is part of the breast shield.

diaphragm is a one-piece item devoid of any holes or openings.

diaphragm is permanently fixed to the outer shell.

diaphragm is a single flexible membrane shaped to include inner and outer substantially cylindrical walls that are generally parallel to the center axis of the nipple tunnel, an annular wall that joins the inner and outer substantially cylindrical walls, and an end wall that sits over the end of the nipple tunnel.

Diaphragm Cap

diaphragm cap is removable.

diaphragm cap forms the front of the outer shell.

diaphragm cap includes an air port that is configured to deliver air pressure to the milk collection hub.

diaphragm cap is configured to fit or latch onto the outer shell with a single push action.

diaphragm cap includes recesses or features configured to be gripped with the fingers of one hand.

diaphragm cap includes a pair of recesses configured to enable the cap to be gripped and removed from the outer shell, and installed into the outer shell, with a single hand.

diaphragm cap is rotatable in the outer shell to adjust the position of the air port on the diaphragm cap.

diaphragm cap includes a passage way for the air tube.

diaphragm cap includes a flat portion such that the milk collection hub can rest on a flat surface positioned on this flat portion.

diaphragm cap is is shaped to fit inside an inner portion of a bra.

diaphragm cap is a transparent or optically clear, dishwasher safe polypropylene, polycarbonate or copolyester, such as Tritan™, diaphragm cap.

Entire System

the system is a closed system.

the system has a capacity of approximately 5 fluid ounces (148 ml).

width of the milk collection hub is of about 5.7 cm in the direction of the central axis of the nipple tunnel.

each milk collection hub is, in-use, bra-worn, for example is shaped to be worn inside a maternity bra.

the system makes less than 50 dB noise at maximum power when the motor is running, and preferably less than 45 dB.

Control Unit

control unit is configured to control suction delivered to one or two wearable milk collection hubs.

control unit houses an air pump subsystem that is configured to generate negative air pressure and transfer negative air pressure to a wearable milk collection hub.

control unit does not house an air pump subsystem but controls an air pump that is external to the control unit

air pump subsystem is held in place between a sound attenuating motor mount and an airflow block, each configured to absorb vibration from the pump unit.

control unit includes a wireless data communications system powered by a rechargeable battery;

control unit includes one or more buttons which are configured to control at least one wearable collection hub.

control unit includes a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the hub.

control unit includes a visual and/or haptic indicator that indicates the activated pumping profile or pattern.

control unit includes a visual and/or haptic indicator that indicates the rechargeable battery status.

control unit includes a USB charging socket connected to the power charging circuit;

multifunction mount is an o-ring.

Airflow Block

airflow block is configured transfer air or suction from the pump unit and also to absorb vibrations from the pump unit.

airflow block is made of a compression moulded silicone.

airflow block is directly connected to the air pump subsystem outlet.

airflow block is located near a solenoid valve.

airflow block is a one-piece item.

control unit is sealed such as to further attenuate sound.

control unit includes an housing with a top portion and a bottom portion.

the bottom and top portions are sealed together using a seal perimeter.

airflow block is integrated with a portion of the seal perimeter.

airflow block connects to an air port or hole for a tube that delivers air to a wearable milk collection hub.

Sound Valve

sound valve is configured to regulate the pressure inside the control unit so that the inside of the control unit remains at ambient pressure and also to attenuate noise from the pump unit escaping from inside the control unit.

sound valve is located on the bottom portion of the control unit.

sound valve includes a small cut that is configured to deform under pressure.

sound valve is made of silicone.

Foam Cap

solenoid foam cap is configured to reduce the speed of air that enters the solenoid valve when the solenoid valve opens to ambient air pressure and hence to reduce the sound of that air entering the solenoid valve.

solenoid foam cap is a one piece item made of plastic.

foam cap includes one or more small opening or holes.

control unit also includes two silencers (or muffler) in which one silencer is connected to the solenoid valve and the other silencer is connected to the motor.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

What is claimed is:

1. A wearable milk collection hub comprising:

a breast shield comprising:

a breast flange;

a nipple tunnel extending from the breast flange, the nipple tunnel comprising

a closed end and a milk port, the milk port being intermediate to the breast flange and the closed end; and an outer edge;

a diaphragm configured to deform to create negative air pressure in the nipple tunnel, at least a part of the diaphragm is arranged over the closed end of the nipple tunnel and concentric with the nipple tunnel; and

an outer shell comprising an outer groove configured to receive the outer edge of the breast shield such that the outer shell is configured to be removably attachable to the breast shield, the outer shell further configured to receive expressed milk via the milk port.

2. The wearable milk collection hub of claim **1**, wherein the outer shell is configured to be removably attachable to the breast shield such that the outer shell is configured to contact the breast shield at a rear end of the outer shell and the breast shield is configured to contact the expressed milk at a front end of the breast shield.

3. The wearable milk collection hub of claim **1**, wherein the outer shell comprises a top end comprising a pouring opening configured to release the expressed milk.

4. The wearable milk collection hub of claim **1**, wherein the outer shell comprises a base comprising a flat portion configured to allow the wearable milk collection hub to rest on a flat surface.

5. The wearable milk collection hub of claim **1**, wherein the breast shield comprises a diaphragm housing part comprising an air hole configured to transfer negative air pressure to the nipple tunnel.

6. The wearable milk collection hub of claim **1**, wherein the diaphragm is configured to be removably mounted between the breast shield and the outer shell.

7. The wearable milk collection hub of claim **1**, wherein the breast shield and the outer shell are substantially transparent, providing to a user placing the wearable milk collection hub onto the user's breast a view of a nipple to facilitate correct nipple alignment, and

wherein the outer shell is configured to support an air port configured to provide an air connection to a control unit via a tube.

8. A wearable milk collection hub configured to connect to an external negative pressure generating control unit comprising:

a breast shield comprising:

a breast flange;

a nipple tunnel extending from the breast flange, the nipple tunnel comprising an end remote from the breast flange and a milk port intermediate to the breast flange and the end; and

a diaphragm housing part;

a diaphragm configured to:

be removably mounted to the diaphragm housing part,

extend over and adjacent to the milk port in a relaxed state, and

deform based on negative air pressure generated by the control unit to create negative air pressure in the nipple tunnel; and

an outer shell comprising a rear end configured to removably attach the outer shell to the breast shield such that the breast shield and the outer shell form a vessel to receive expressed milk via the milk port, a front end opposing the rear end, the front end comprising a curvature, a base intermediate to the rear end and the front end, and a top end opposing the base, the top end comprising a pouring opening configured to release the expressed milk.

9. The wearable milk collection hub of claim **8**, wherein a structure comprising the diaphragm is configured to be at least partially arranged over the closed end of the nipple tunnel.

10. The wearable milk collection hub of claim **8**, further comprising an air port configured to provide an air connection to the control unit via a tube.

11. The wearable milk collection hub of claim **10**, further comprising a movable cap positioned over the air port.

12. The wearable milk collection hub of claim **11**, wherein the movable cap is disposed on the front end of the outer shell.

13. The wearable milk collection hub of claim **8**, wherein the breast shield and the outer shell are substantially transparent, providing to a user placing the wearable milk collection hub onto the user's breast a view of a nipple to facilitate correct nipple alignment, and

wherein the wearable milk collection hub is shaped to be worn inside a bra.

14. The wearable milk collection hub of claim **8**, wherein the rear end of the outer shell is configured to receive an outer edge of the breast shield such that an air-tight seal is formed between the breast shield and the outer shell.

15. The wearable milk collection hub of claim **8**, wherein the breast shield is semi-rigid.

16. The wearable milk collection hub of claim **8**, wherein the base comprises a flat portion configured to allow the wearable milk collection hub to rest on a flat surface.

17. A breast pump system comprising:

a control unit comprising:

a battery, and

a pump configured to be powered by the battery and to generate negative air pressure; and

a wearable milk collection hub configured to connect to the control unit via an air line, the wearable milk collection hub comprising:

a breast shield comprising:

a breast flange; and

a nipple tunnel extending from the breast flange;

a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel;

an outer shell comprising a rear end configured to removably attach to the breast shield and, an interior volume between the outer shell and the breast shield defining a chamber to receive expressed milk; and

a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell, the front end being opposite to the rear end, the diaphragm cap forms a central region on a front surface of the outer shell.

18. The breast pump system of claim **17**, wherein the breast shield comprises an outer edge configured to be received by the rear end of the outer shell.

19. The breast pump system of claim **17**, wherein the interior volume is bounded by the rear end of the outer shell and a front end of the breast shield.

20. The breast pump system of claim **17**, wherein the control unit further comprises:

a wireless data communications system configured to be powered by the battery;

one or more buttons configured to control the wearable milk collection hub;

at least one of a visual indicator or a haptic indicator configured to indicate the activated pumping profile or pattern;

at least one of a visual indicator or a haptic indicator configured to indicate a status of the battery; and

a Universal Serial Bus (USB) charging socket configured to be connected to a power charging circuit.

21. The breast pump system of claim **17**, further comprising a milk port through which the expressed milk flows into the chamber.

22. The breast pump system of claim **21**, wherein the diaphragm is configured to extend over and adjacent to the milk port in a relaxed state.

23. The breast pump system of claim **21**, further comprising a non-return valve configured to be mounted to the milk port.

24. The breast pump system of claim **17**, wherein the diaphragm cap comprises an air port configured to receive an end of the air line.

25. The breast pump system of claim **24**, wherein the diaphragm cap is configured such that the air port can be located above the nipple tunnel.

26. The breast pump system of claim **17**, wherein the diaphragm cap comprises a pair of recessed finger grip features.

27. The breast pump system of claim **17**, wherein at least a part of the diaphragm is arranged concentric with the nipple tunnel.

28. A breast pump system comprising:

a control unit comprising:

a battery, and

a pump configured to be powered by the battery and to generate negative air pressure; and

a wearable milk collection hub configured to connect to the control unit via an air line, the wearable milk collection hub comprising:

a breast shield comprising:

a breast flange; and

a nipple tunnel extending from the breast flange;

a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel, at least a part of the diaphragm is arranged concentric with the nipple tunnel;

an outer shell comprising a rear end configured to removably attach to the breast shield, an interior volume between the outer shell and the breast shield defining a chamber to receive expressed milk; and

a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell, the front end being opposite to the rear end.

29. The breast pump system of claim **28**, wherein the interior volume is bounded by the rear end of the outer shell and a front end of the breast shield.

30. The breast pump system of claim **28**, wherein the diaphragm cap forms a central region on a front surface of the outer shell.

31. The breast pump system of claim **28**, further comprising a milk port through which the expressed milk flows into the chamber, wherein the diaphragm is configured to extend over and adjacent to the milk port in a relaxed state.

32. The breast pump system of claim **28**, wherein the diaphragm cap comprises an air port configured to receive an end of the air line.

33. The breast pump system of claim **28**, wherein the diaphragm cap comprises a pair of recessed finger grip features.

* * * * *

Exhibit 26

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(12) United States Patent
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(54) **BREAST PUMP SYSTEM**

(71) Applicant: **CHIARO TECHNOLOGY LIMITED**, London (GB)

(72) Inventors: **Jonathan O'Toole**, Bristol (GB); **Adam Rollo**, London (GB); **Andrew Carr**, Edinburgh (GB)

(73) Assignee: **Chiaro Technology Limited**, London (GB)

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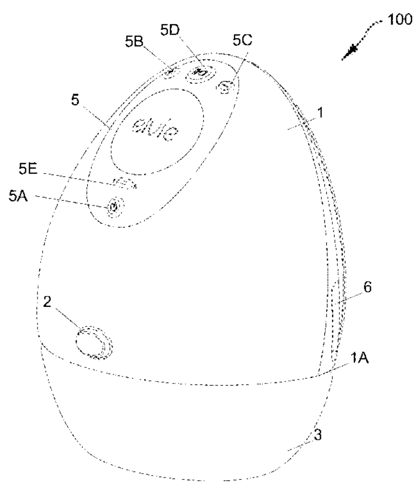
Primary Examiner — Nathan R Price
Assistant Examiner — Courtney B Fredrickson
(74) *Attorney, Agent, or Firm* — Sterne, Kessler, Goldstein & Fox P.L.L.C.

(57) **ABSTRACT**

The invention is a wearable breast pump system including a housing shaped at least in part to fit inside a bra and a piezo air-pump. The piezo air-pump is fitted in the housing and forms part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure. The diaphragm is removably mounted on a breast shield.

29 Claims, 44 Drawing Sheets



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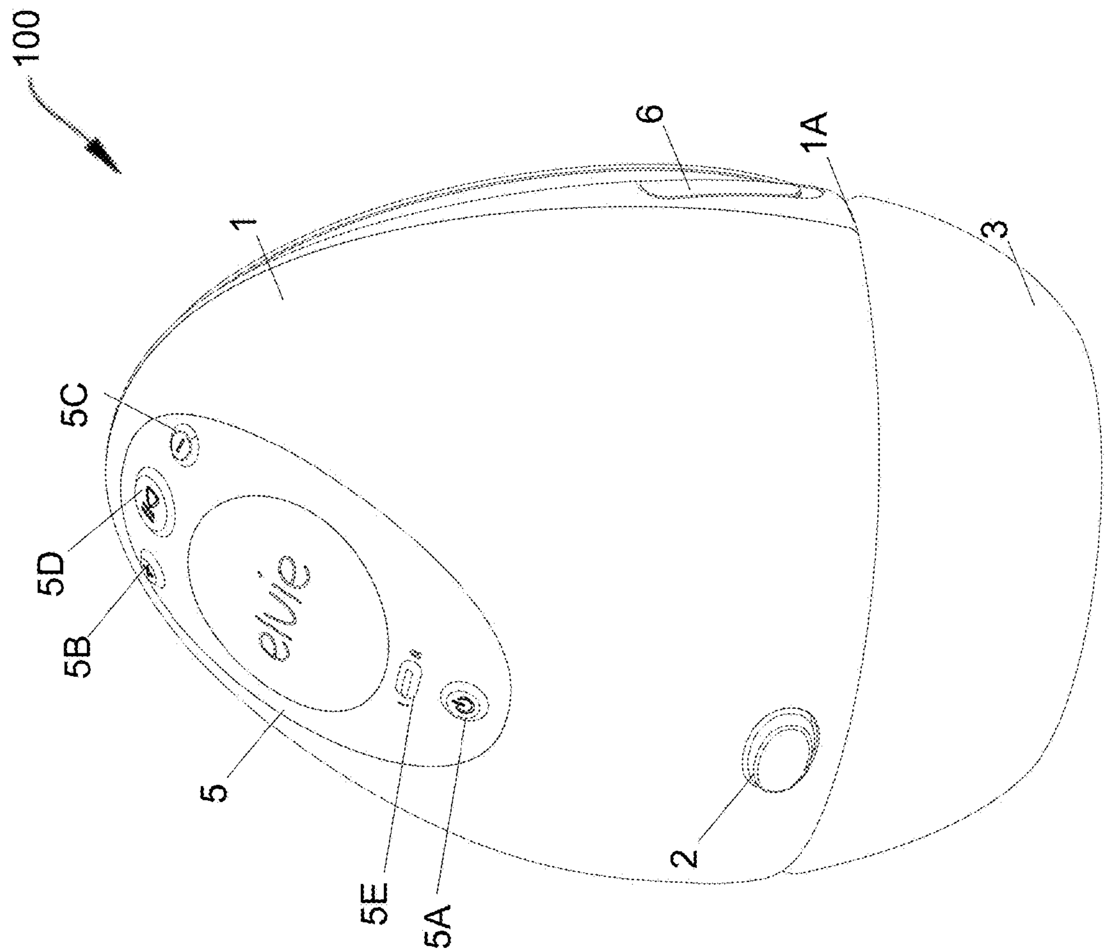


FIGURE 1

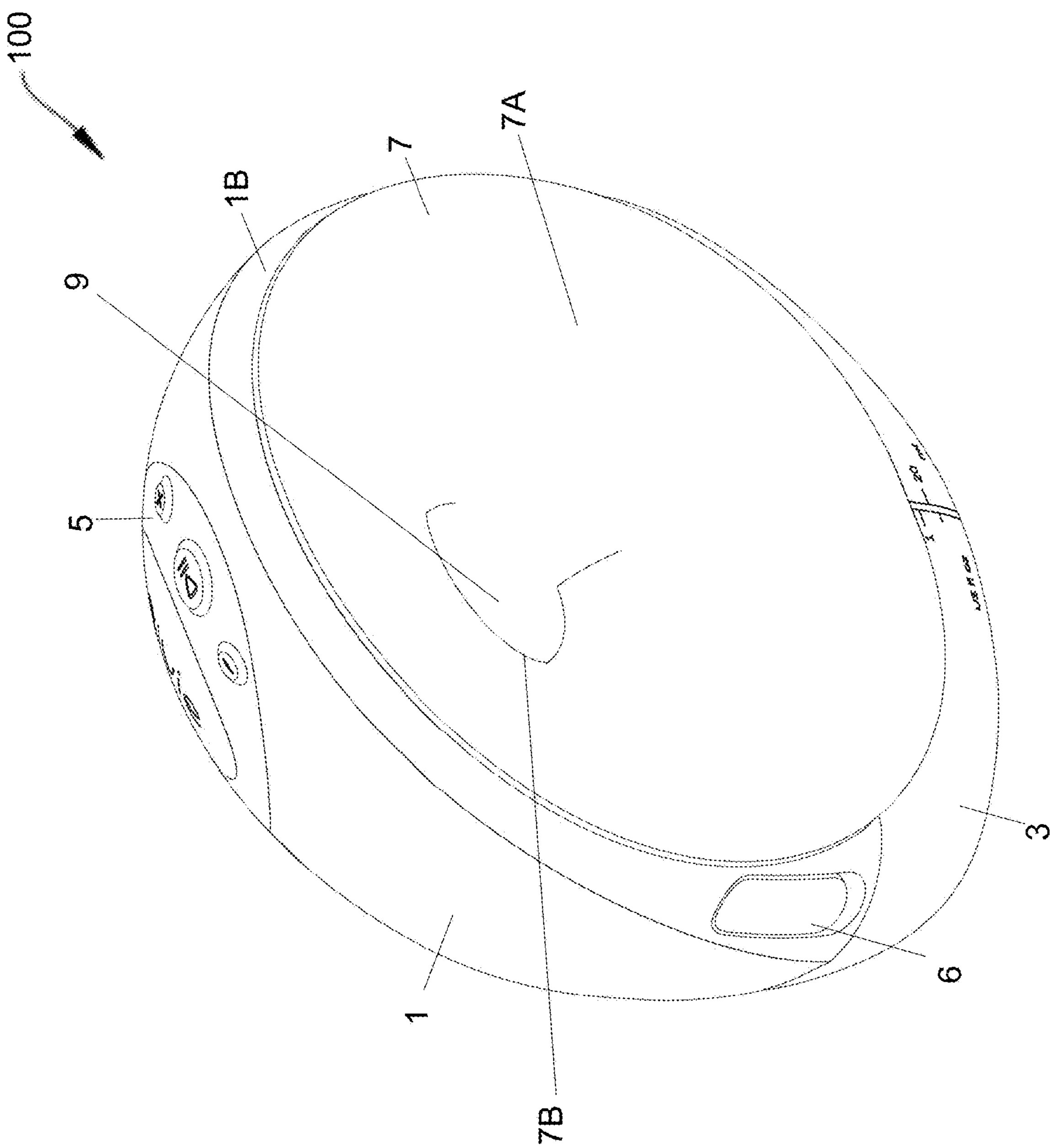


FIGURE 2

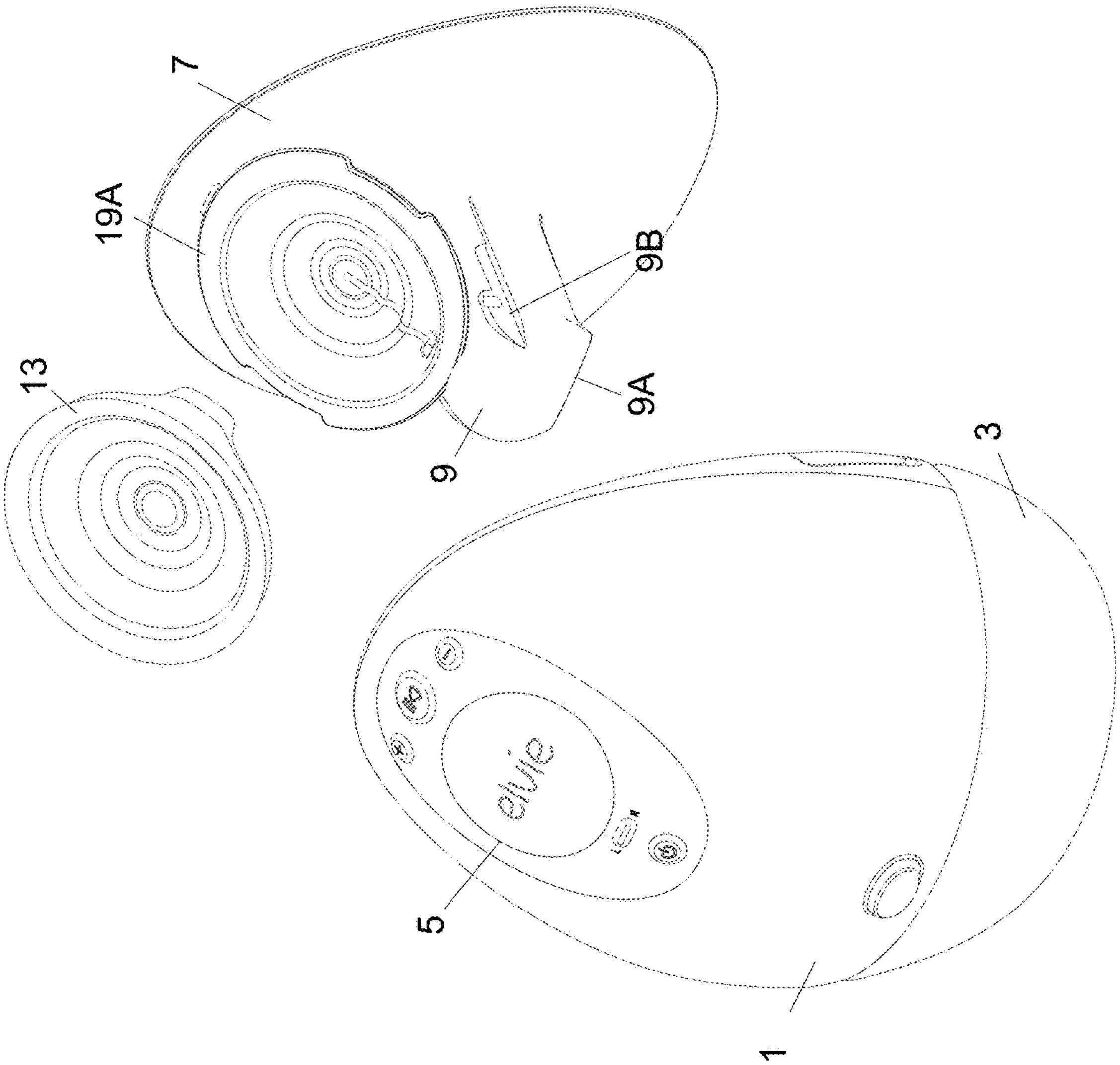


FIGURE 3

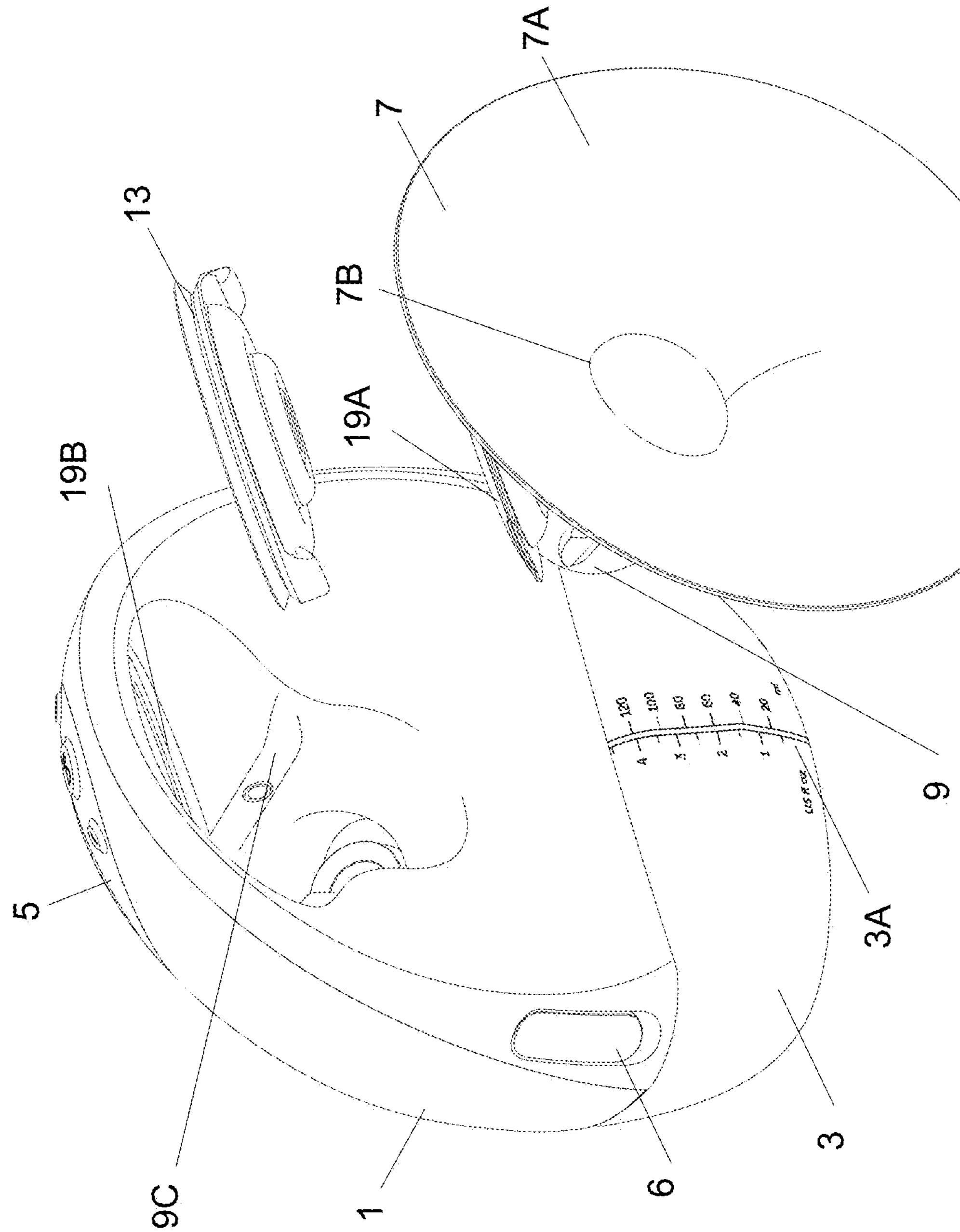


FIGURE 4

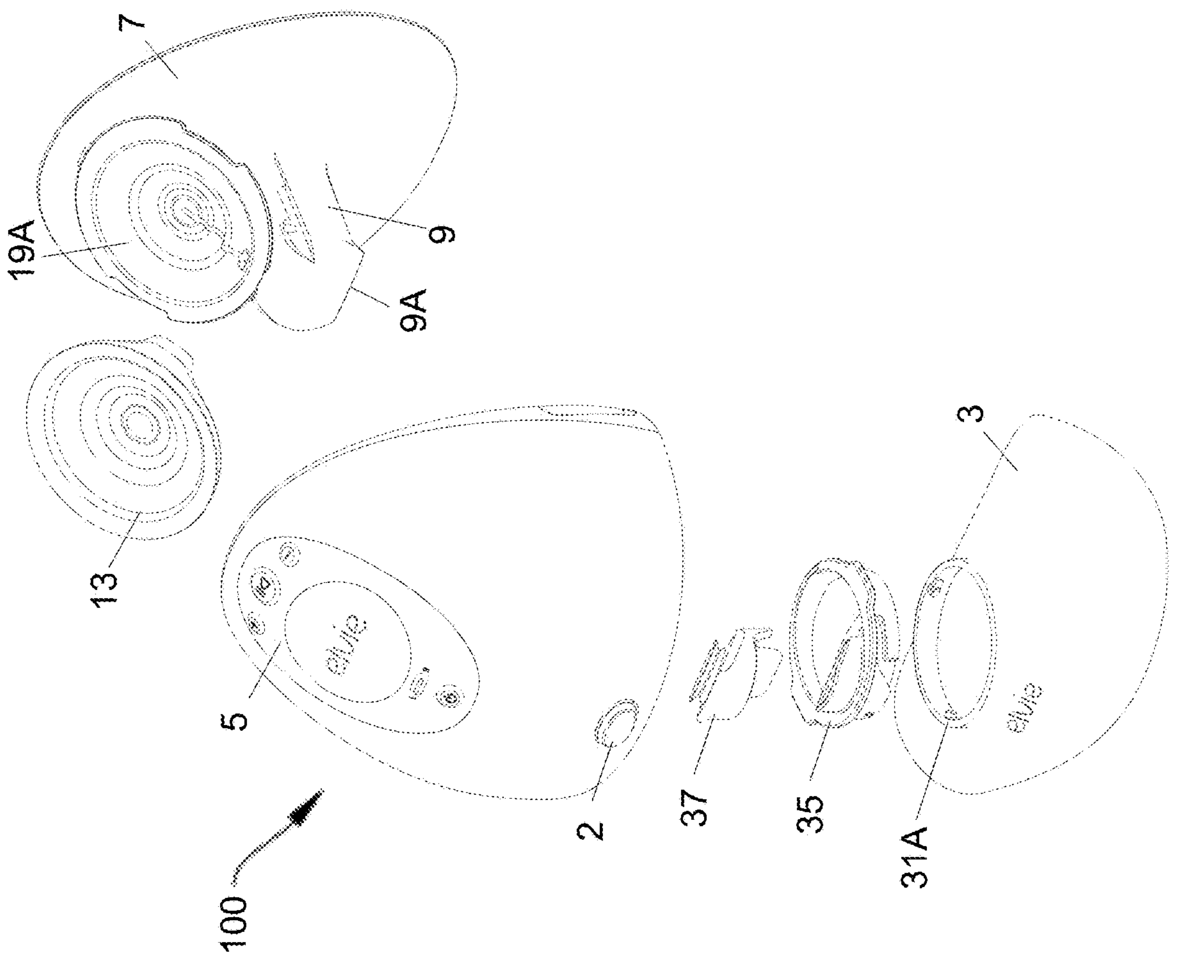


FIGURE 5

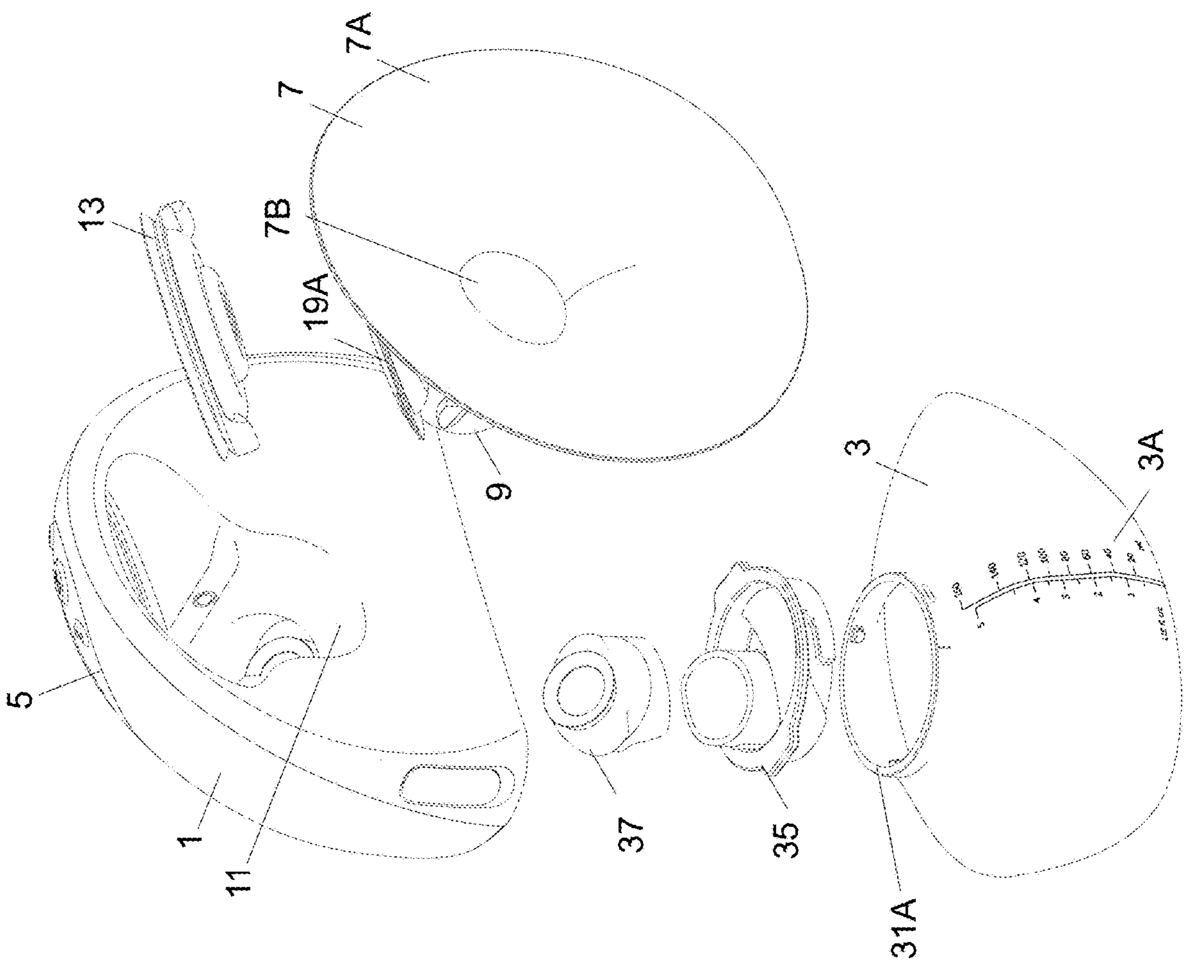


FIGURE 6

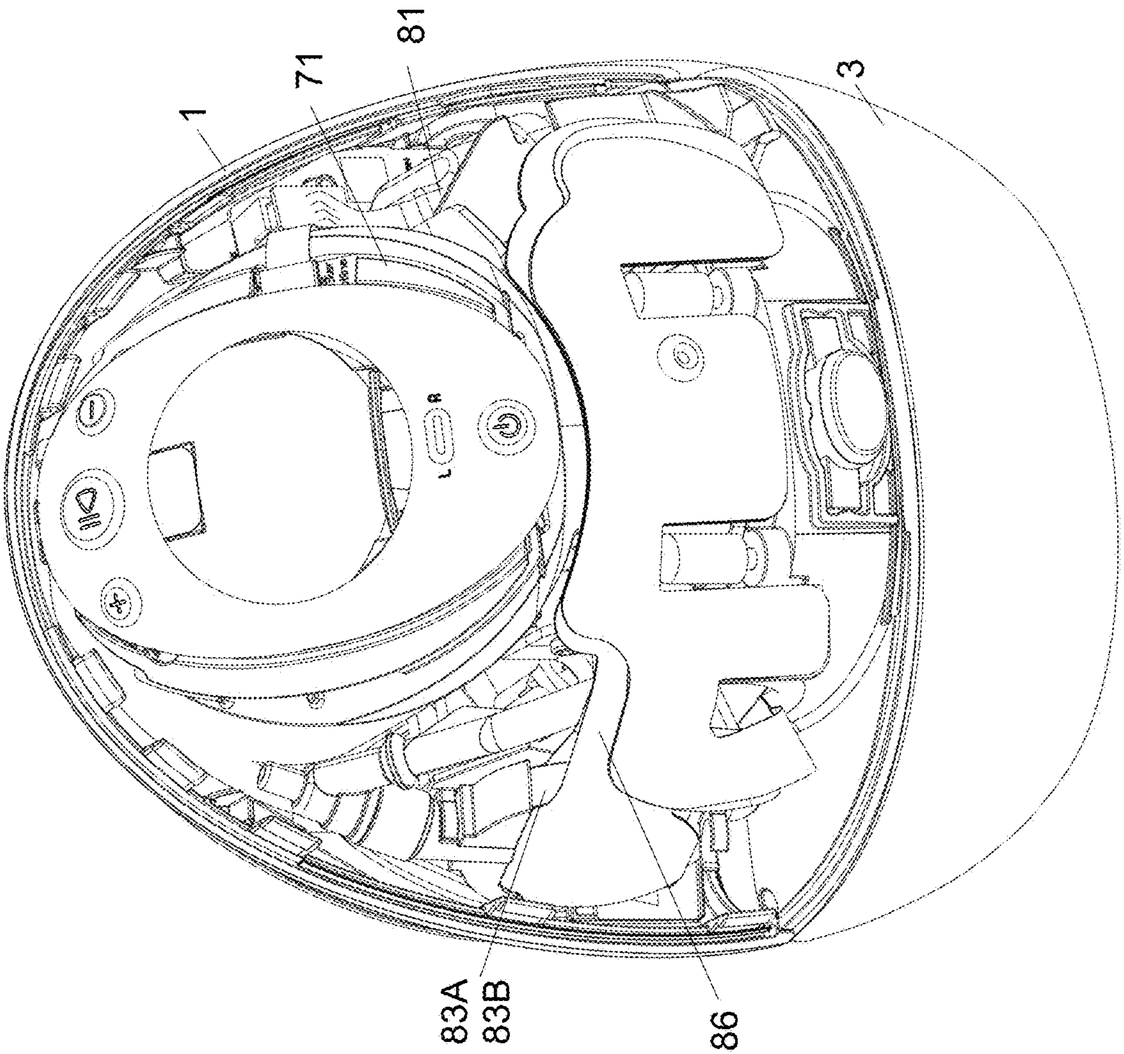


FIGURE 7

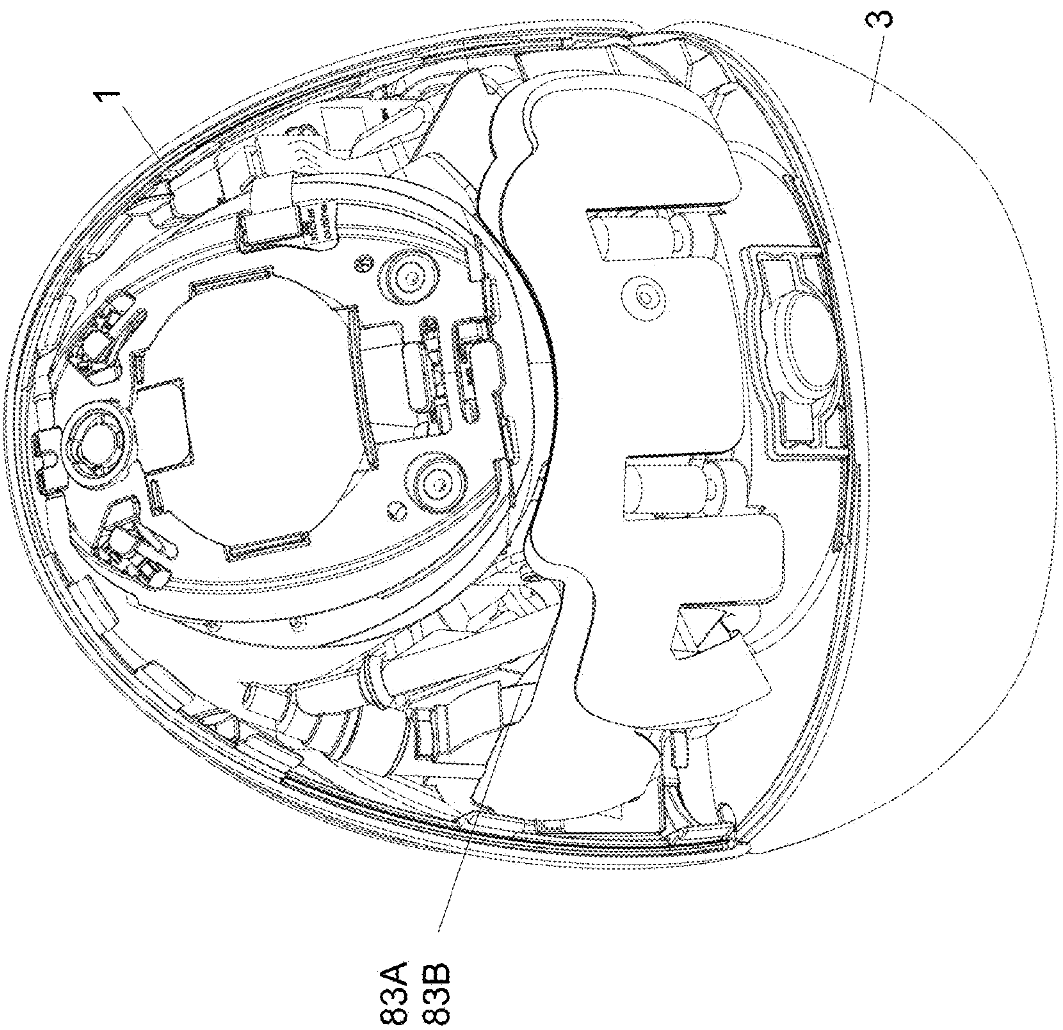


FIGURE 8

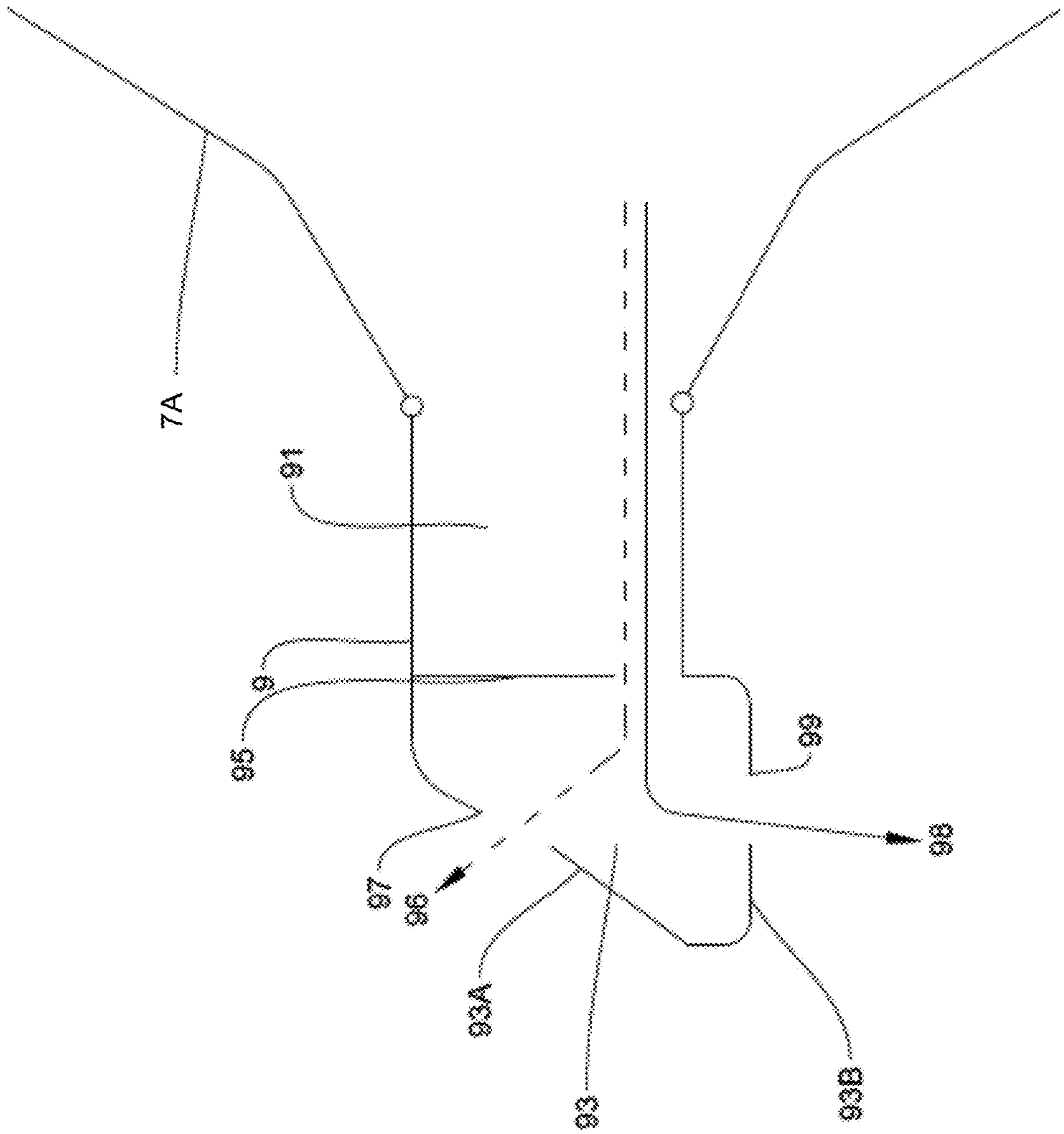


FIGURE 9

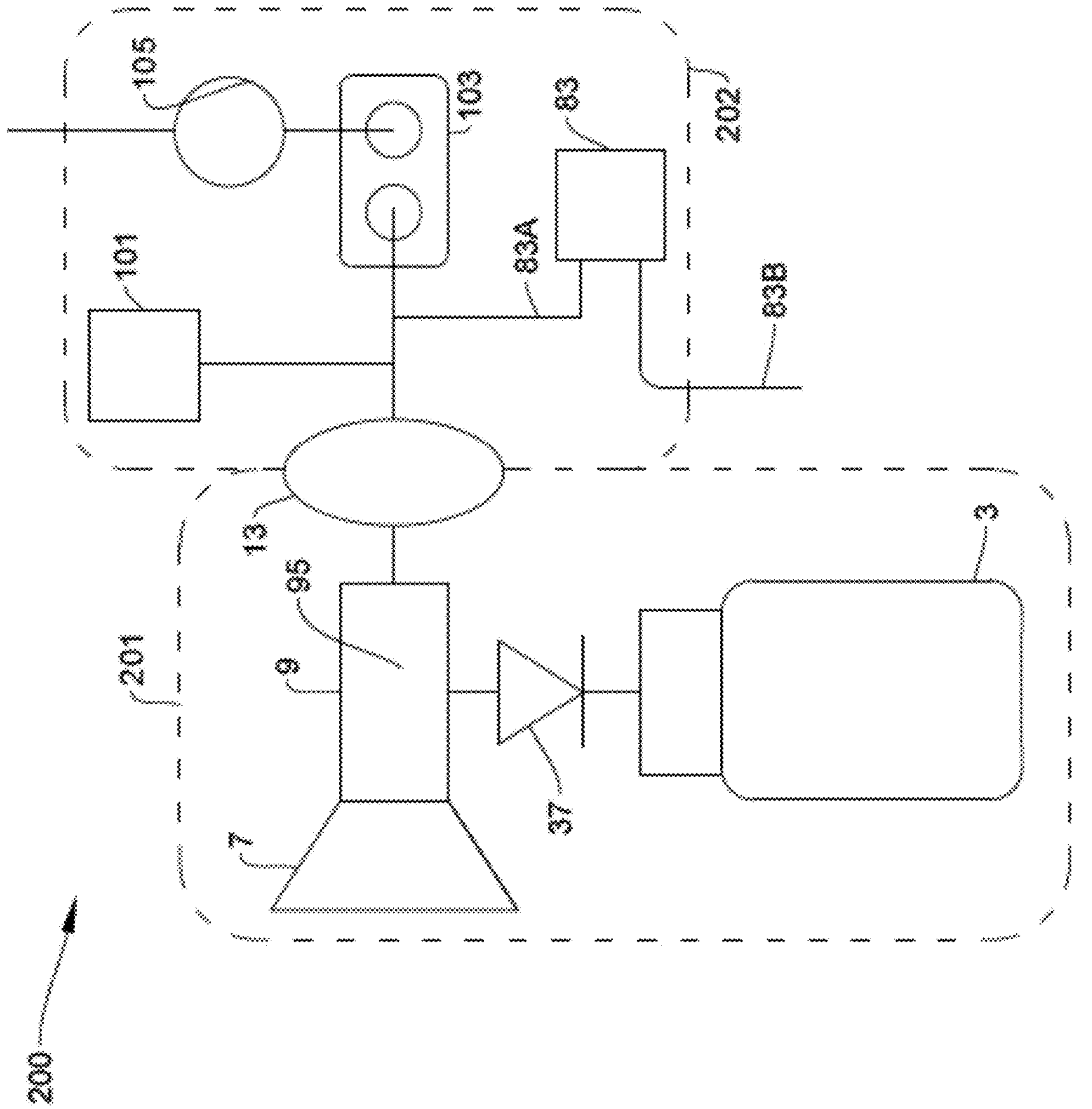


FIGURE 10

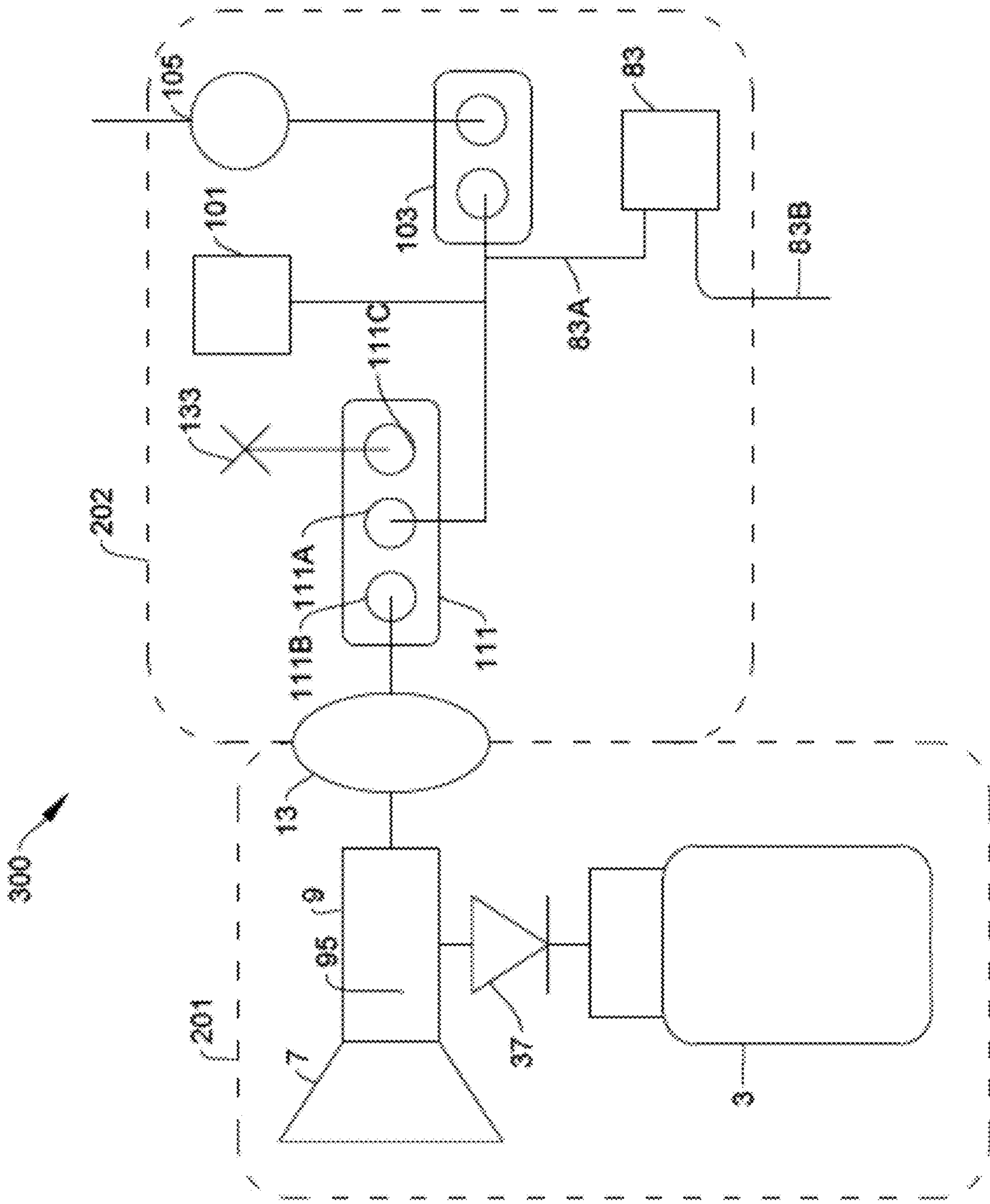

300
202
105
101
103
83
83A
83B
111C
133
111A
111B
111
13
9
95
201
7
37
3

FIGURE 11

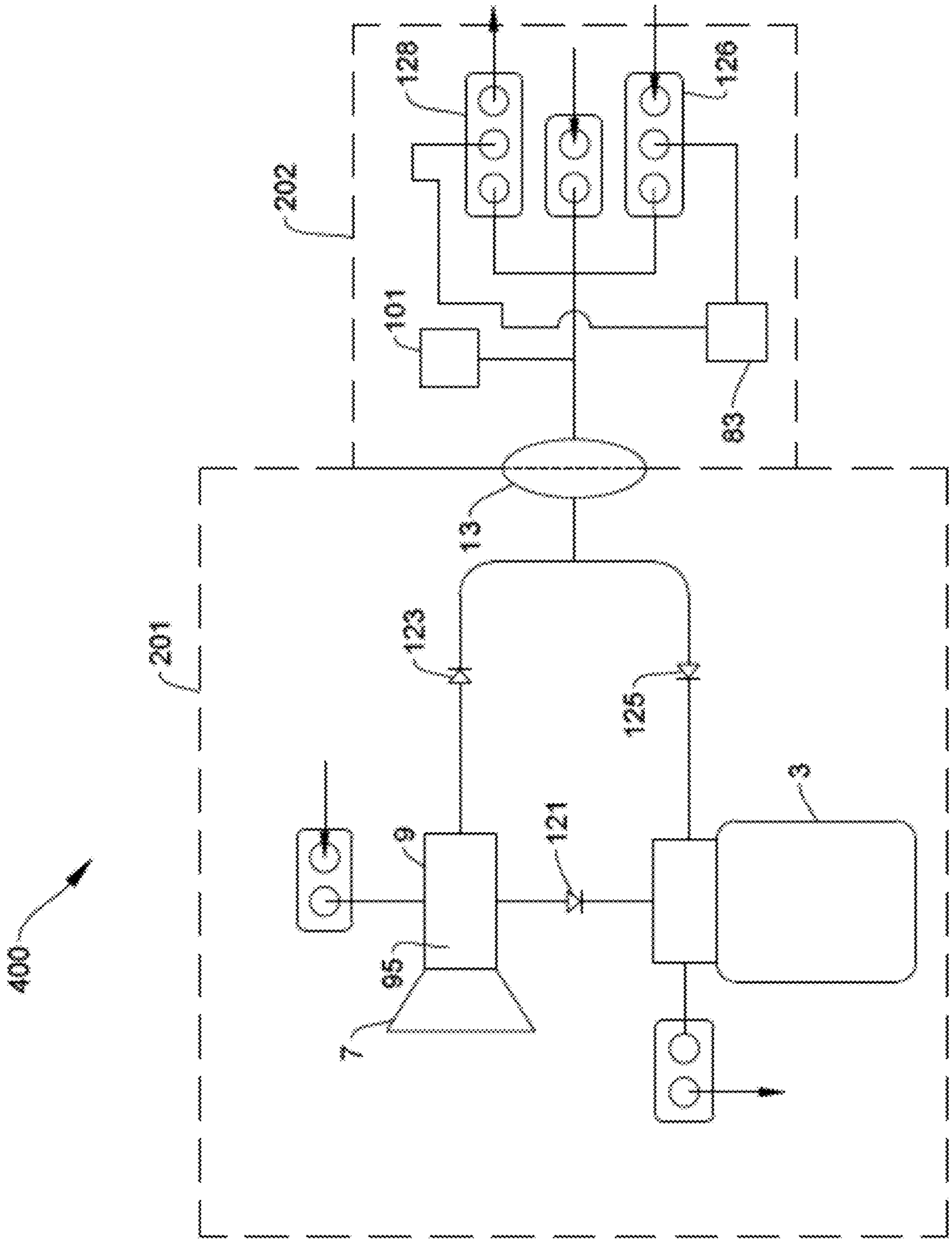


FIGURE 12

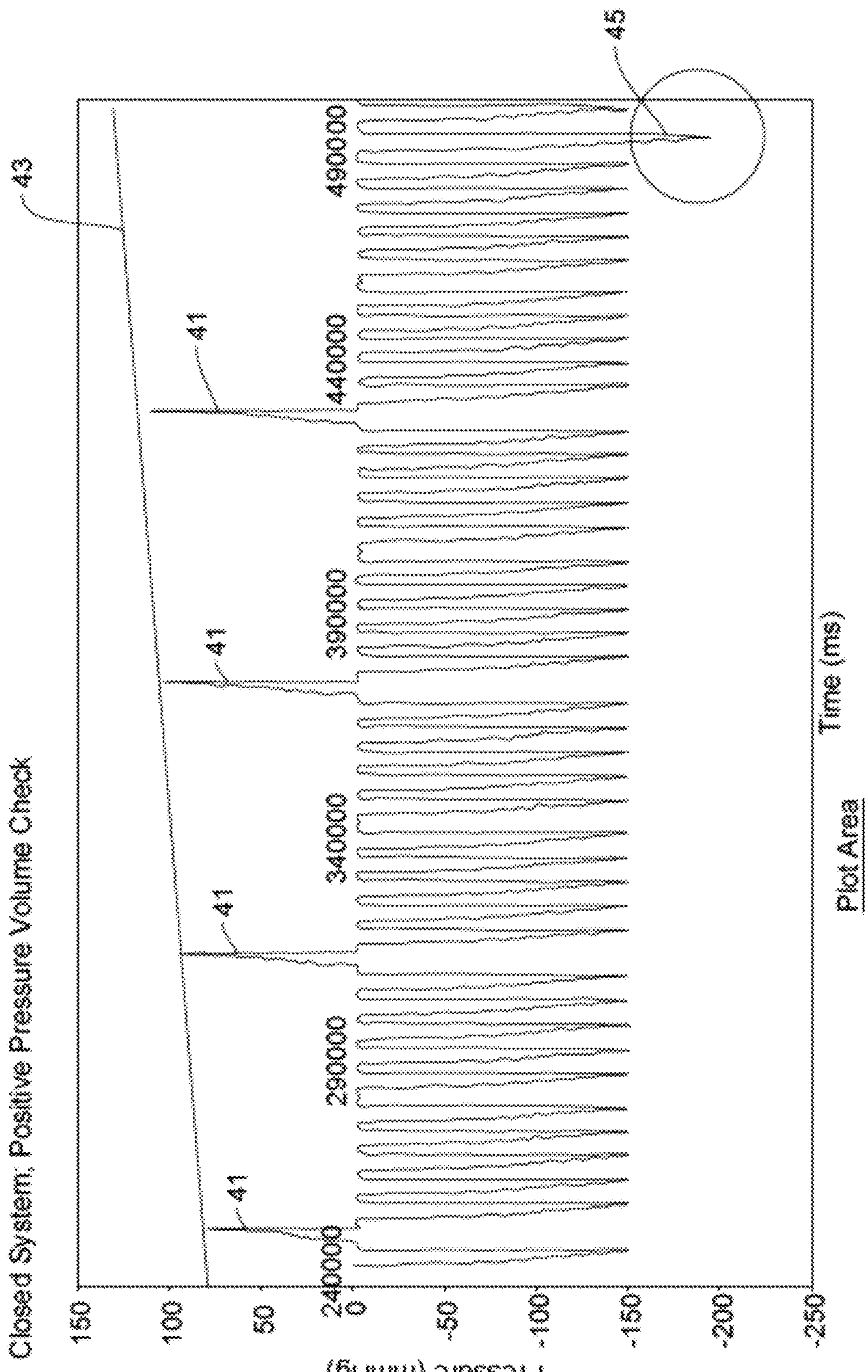

Closed System; Positive Pressure Volume Check
Pressure (mmHg)
150
100
50
0
-50
-100
-150
-200
-250
240000
290000
340000
390000
440000
490000
Time (ms)
Plot Area
41
41
41
41
43
45

FIGURE 13

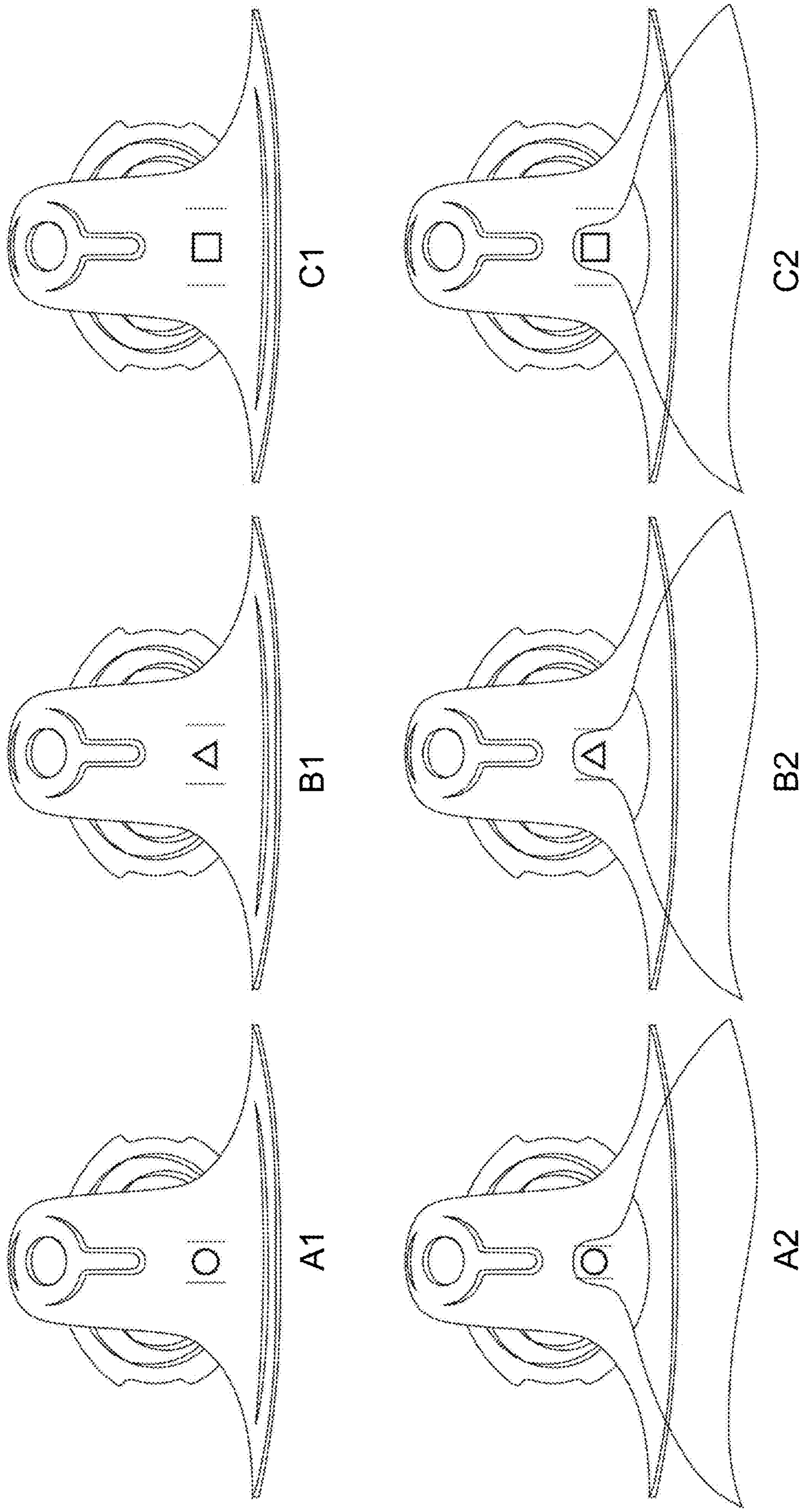


FIGURE 14

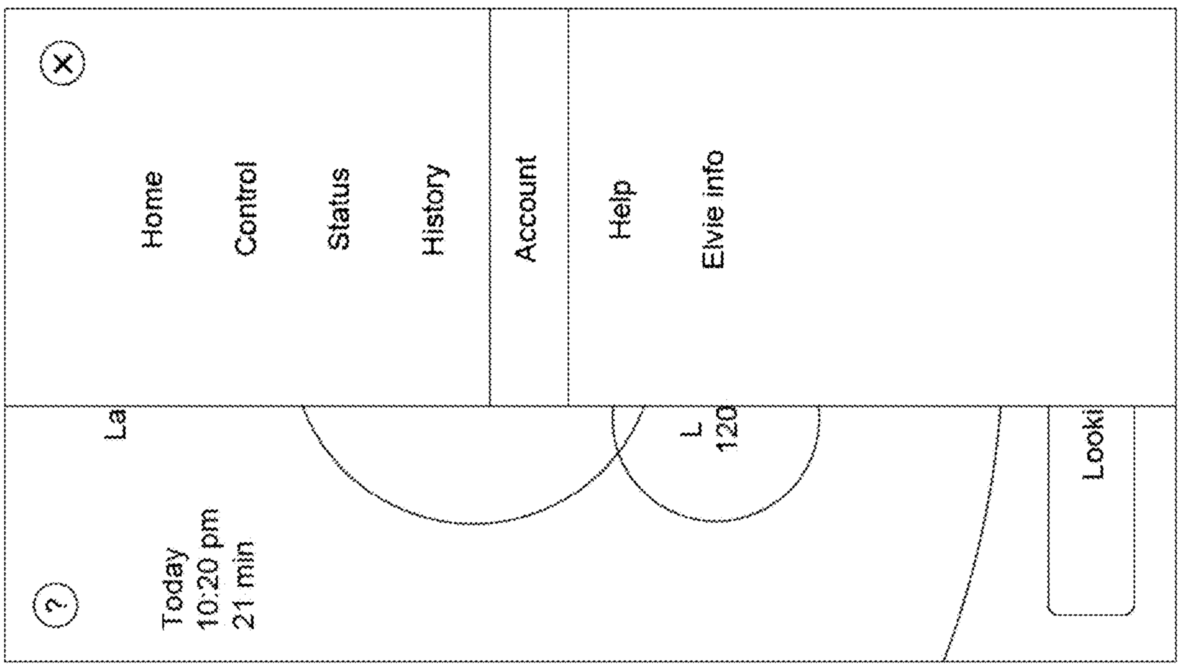

Home
Control
Status
History
Account
Help
Elvie info
La
Today
10:20 pm
21 min
L
120
Looki

FIGURE 15

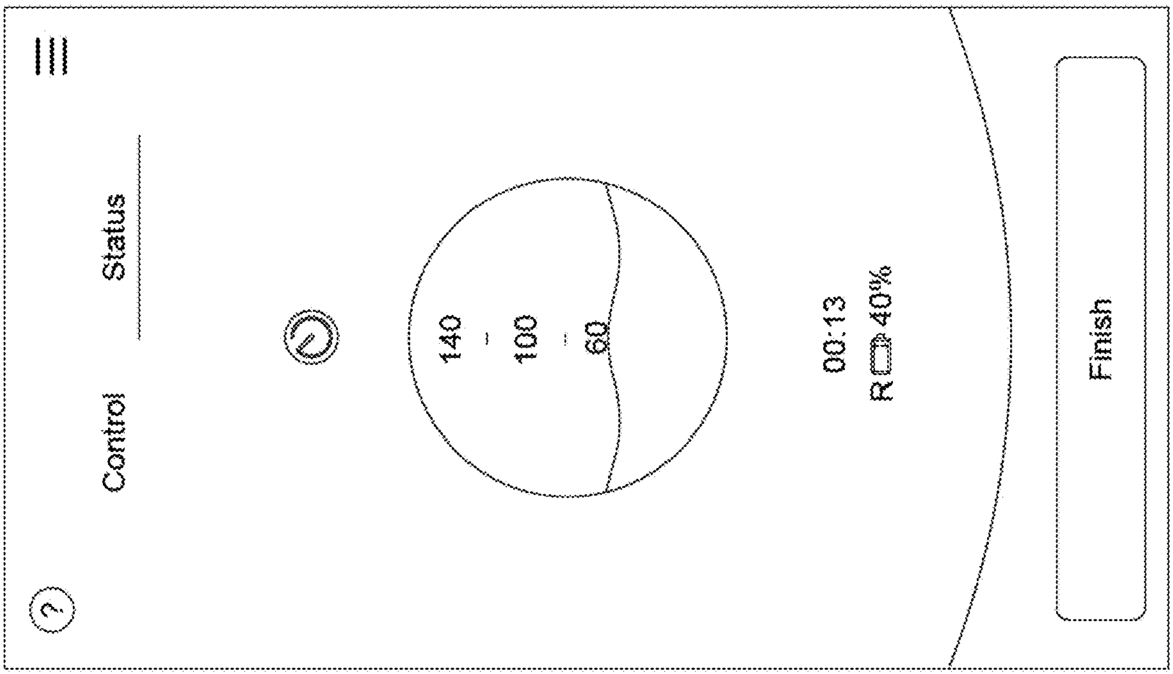


FIGURE 16

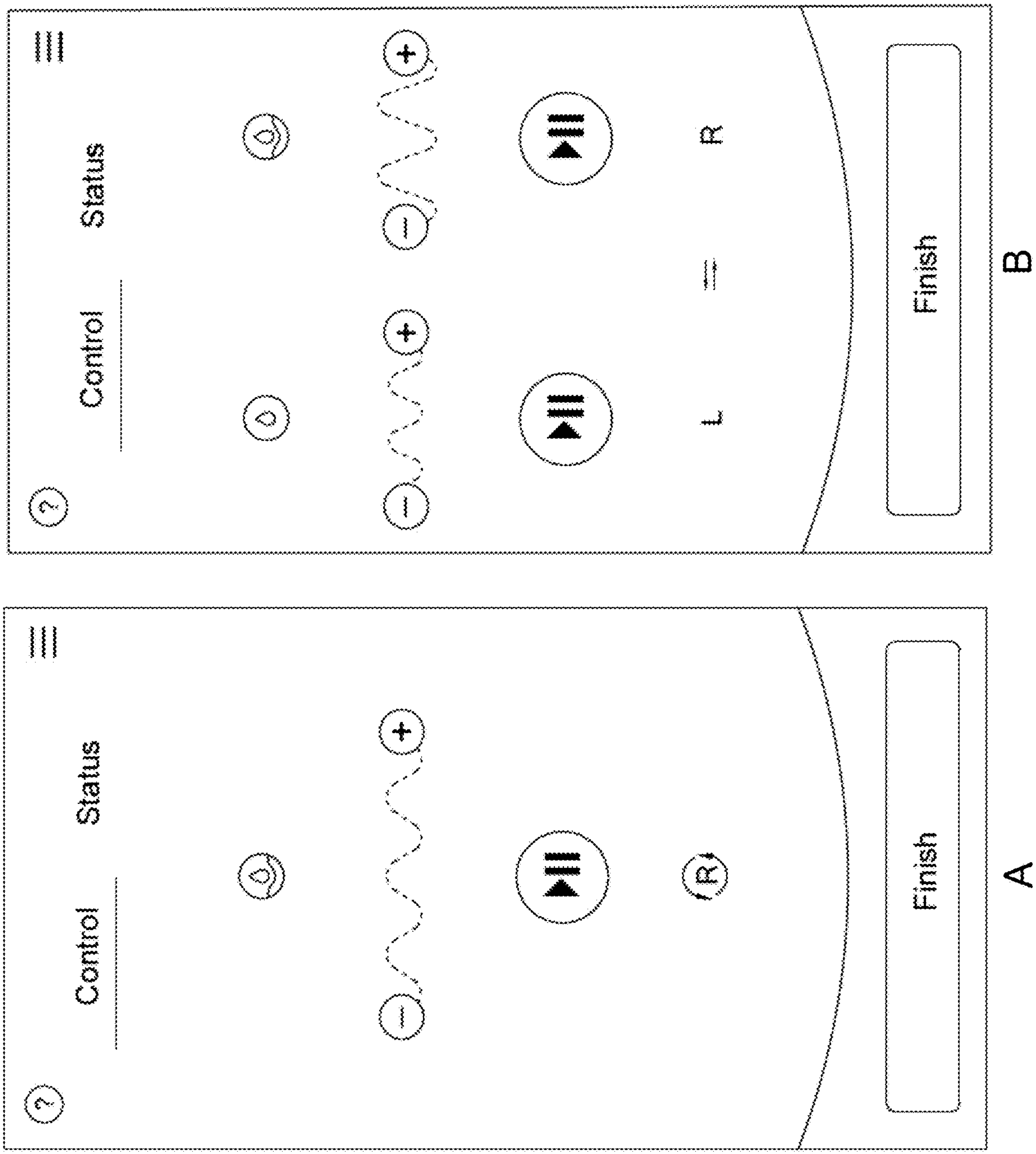


FIGURE 17

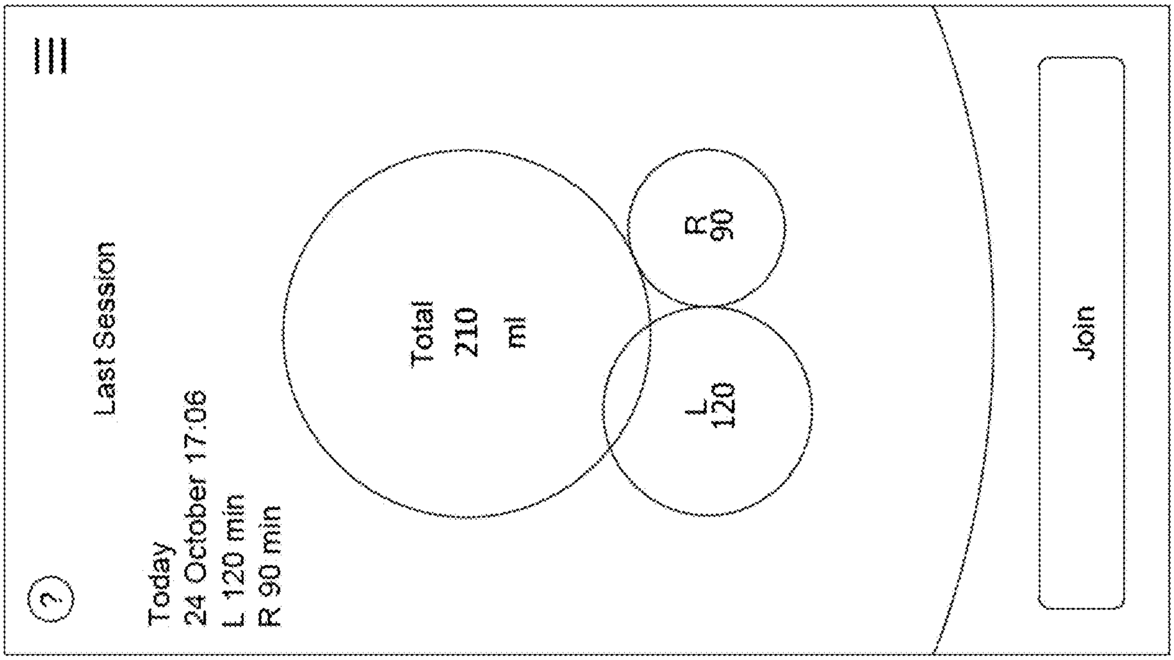

Last Session
Today
24 October 17:06
L 120 min
R 90 min
Total
210
ml
R
90
L
120
Join

FIGURE 18

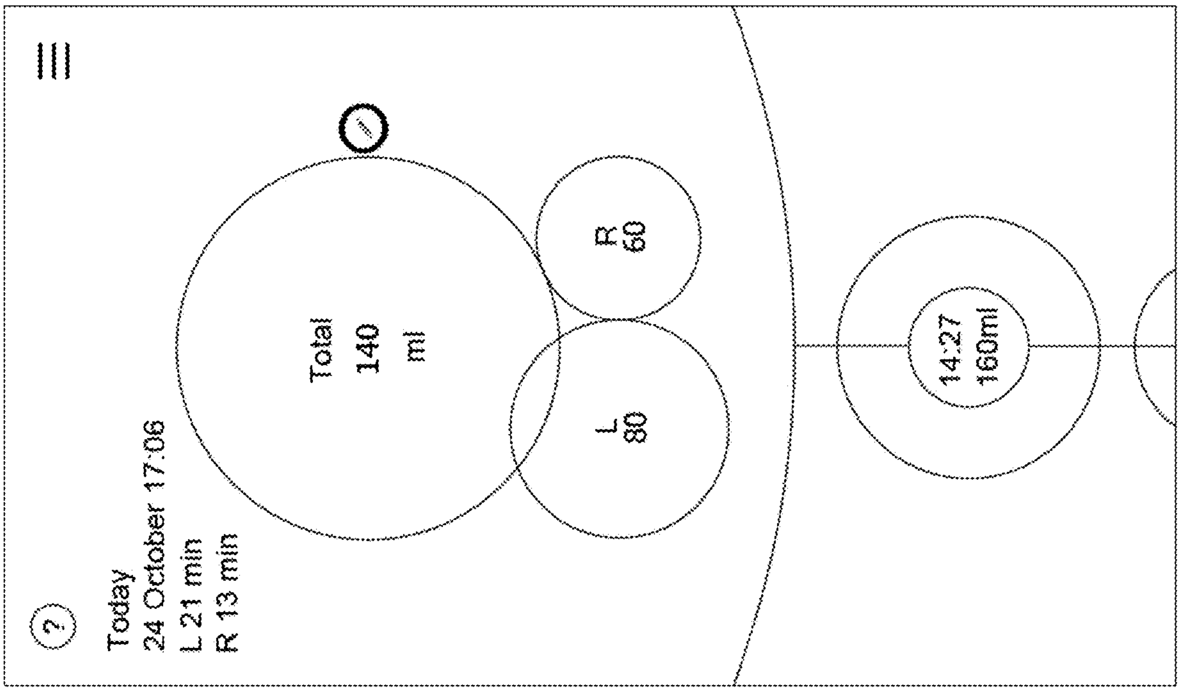

Today
24 October 17:06
L 21 min
R 13 min
Total
140
ml
R
60
L
80
14:27
160ml

FIGURE 19

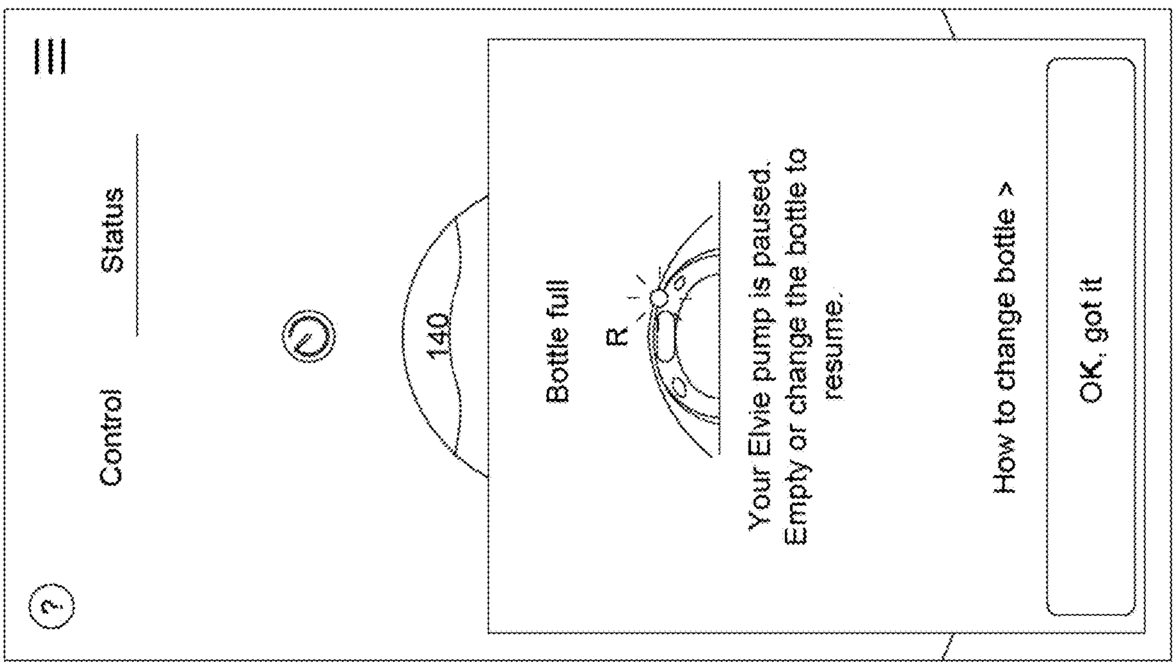

Control
Status
140
Bottle full
R
Your Elvie pump is paused.
Empty or change the bottle to resume.
How to change bottle >
OK, got it

FIGURE 20

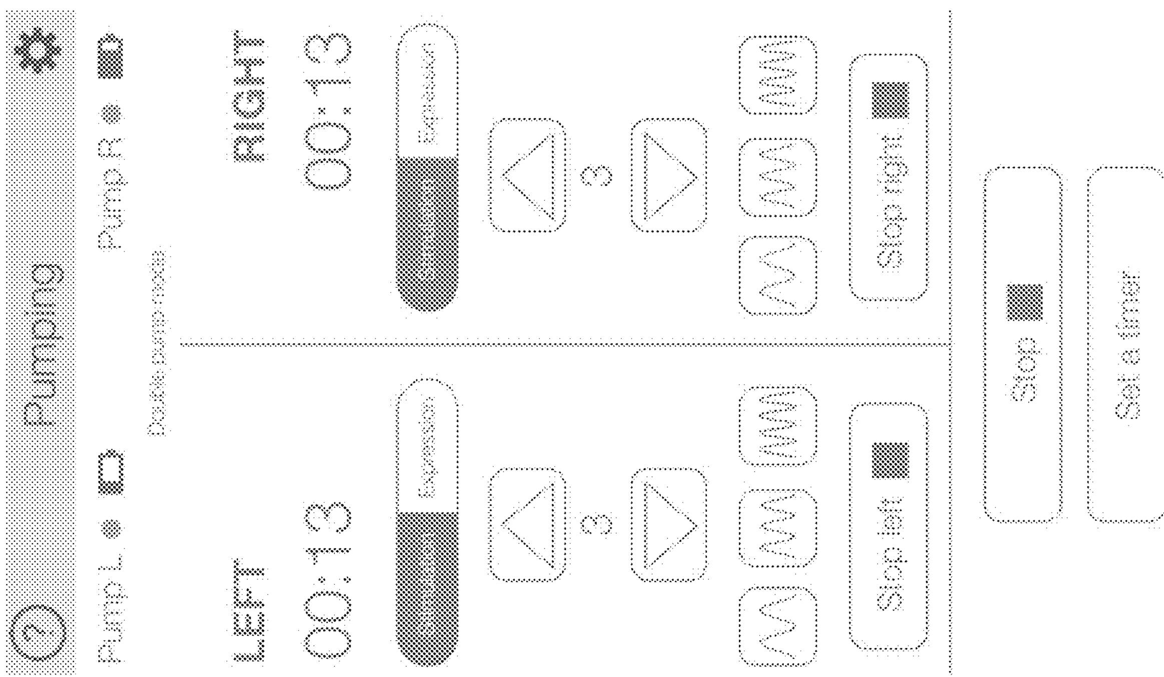
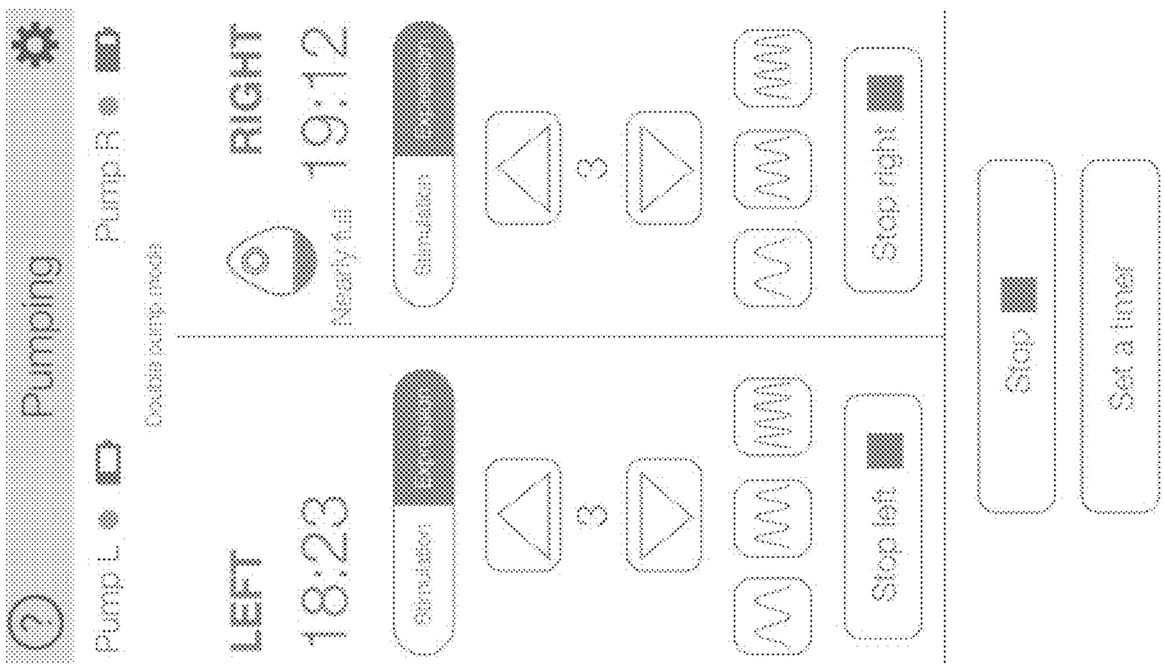

Pumping
Pump L
Pump R
Double pump mode
LEFT
00:13
Expression
3
Stop left
RIGHT
00:13
Expression
3
Stop right
Stop
Set a timer

FIGURE 21



Pumping
Pump L
Pump R
Double pump mode
LEFT
18:23
RIGHT
19:12
Nearly full
Stimulation
3
Stimulation
3
Stop left
Stop right
Stop
Set a timer

FIGURE 22

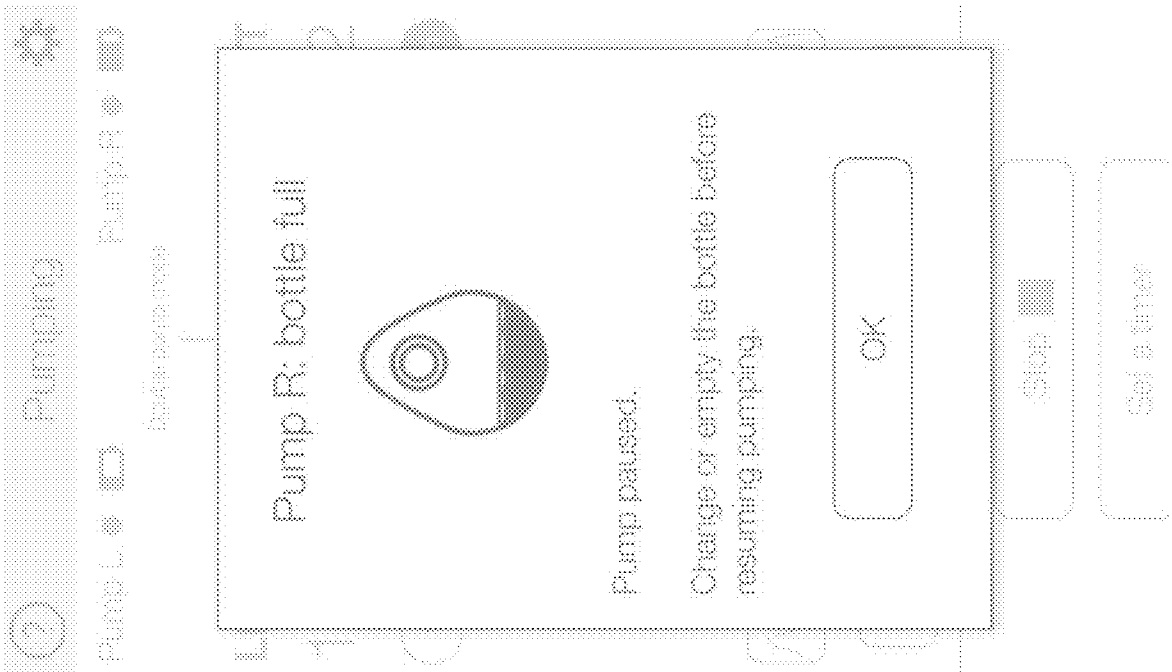

Pumping
Pump R: bottle full
Pump paused.
Charge or empty the bottle before resuming pumping.
OK
Stop
Set a timer

FIGURE 23


Stopped
Pump L
Pump R
Double pump mode
LEFT
21:02
STOPPED
RIGHT
20:38
STOPPED
Total volume in bottle:
60 ml
Total volume in bottle:
65 ml
Tick if you emptied or changed the bottle
Tick if you emptied or changed the bottle
Resume left
Resume right
Resume
End session

FIGURE 24

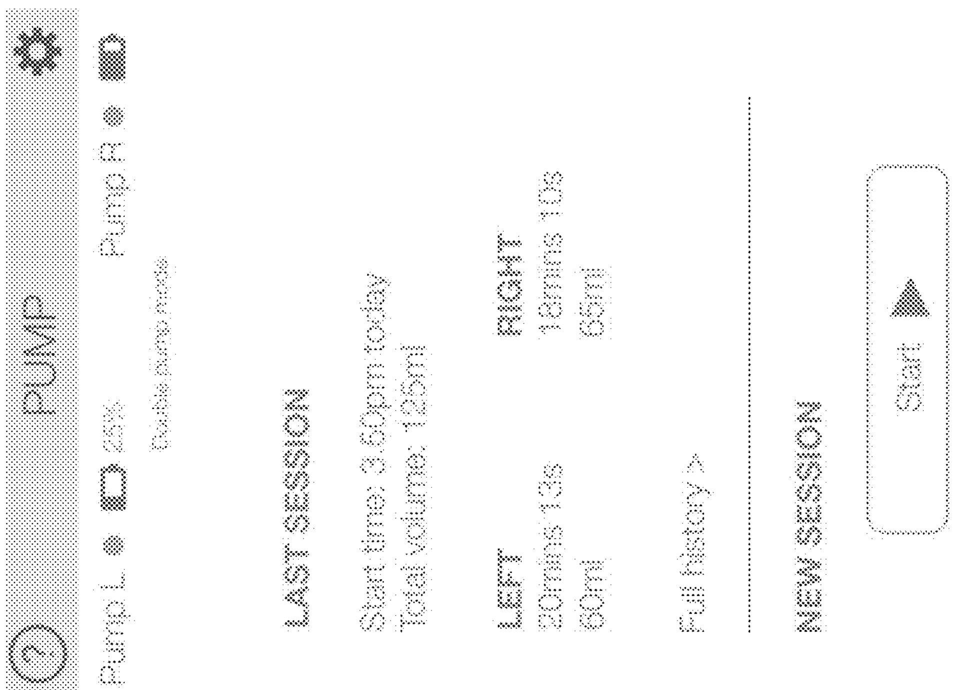

PUMP
Pump L
25%
Pump R
Double pump mode
LAST SESSION
Start time: 3.50pm today
Total volume: 125ml
LEFT
20mins 13s
60ml
RIGHT
18mins 10s
65ml
Full history >
NEW SESSION
Start

FIGURE 25

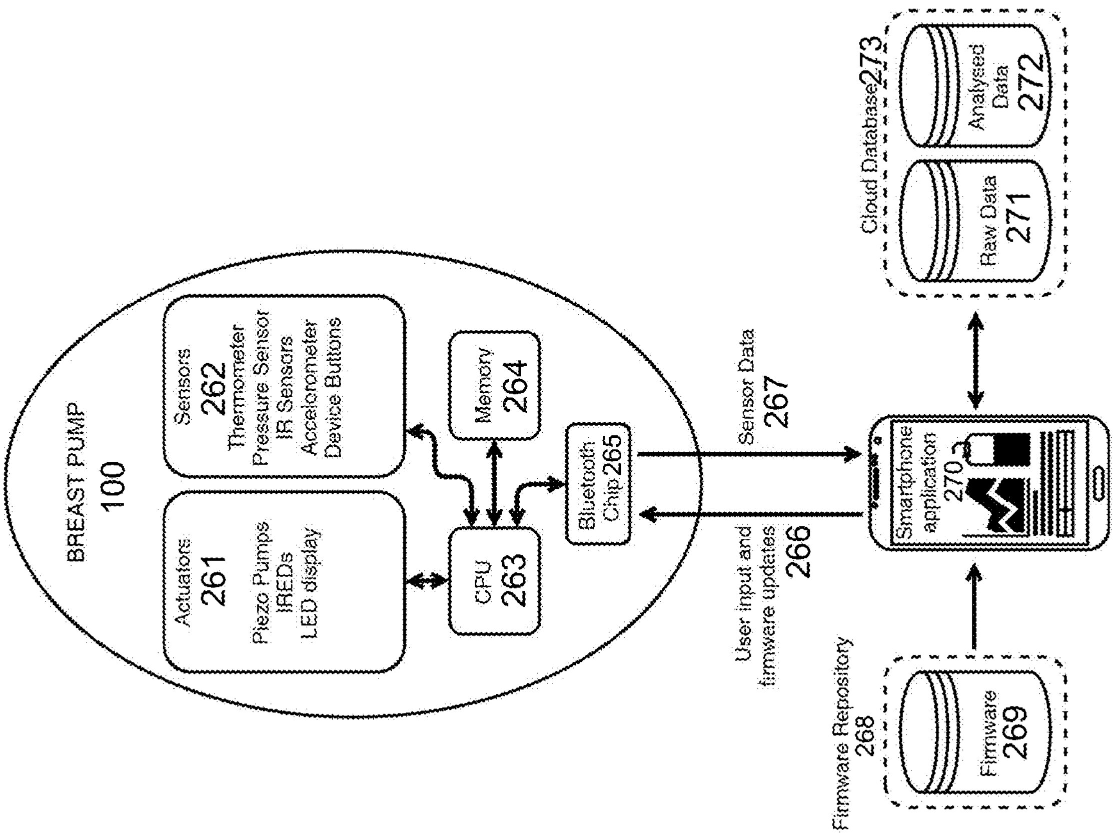

BREAST PUMP
100
Actuators
261
Piezo Pumps
IREDs
LED display
Sensors
262
Thermometer
Pressure Sensor
IR Sensors
Accelerometer
Device Buttons
CPU
263
Memory
264
Bluetooth Chip 265
Sensor Data
267
User input and firmware updates
266
Smartphone application
270
Firmware Repository
268
Firmware
269
Cloud Database 273
Raw Data
271
Analysed Data
272

FIGURE 26

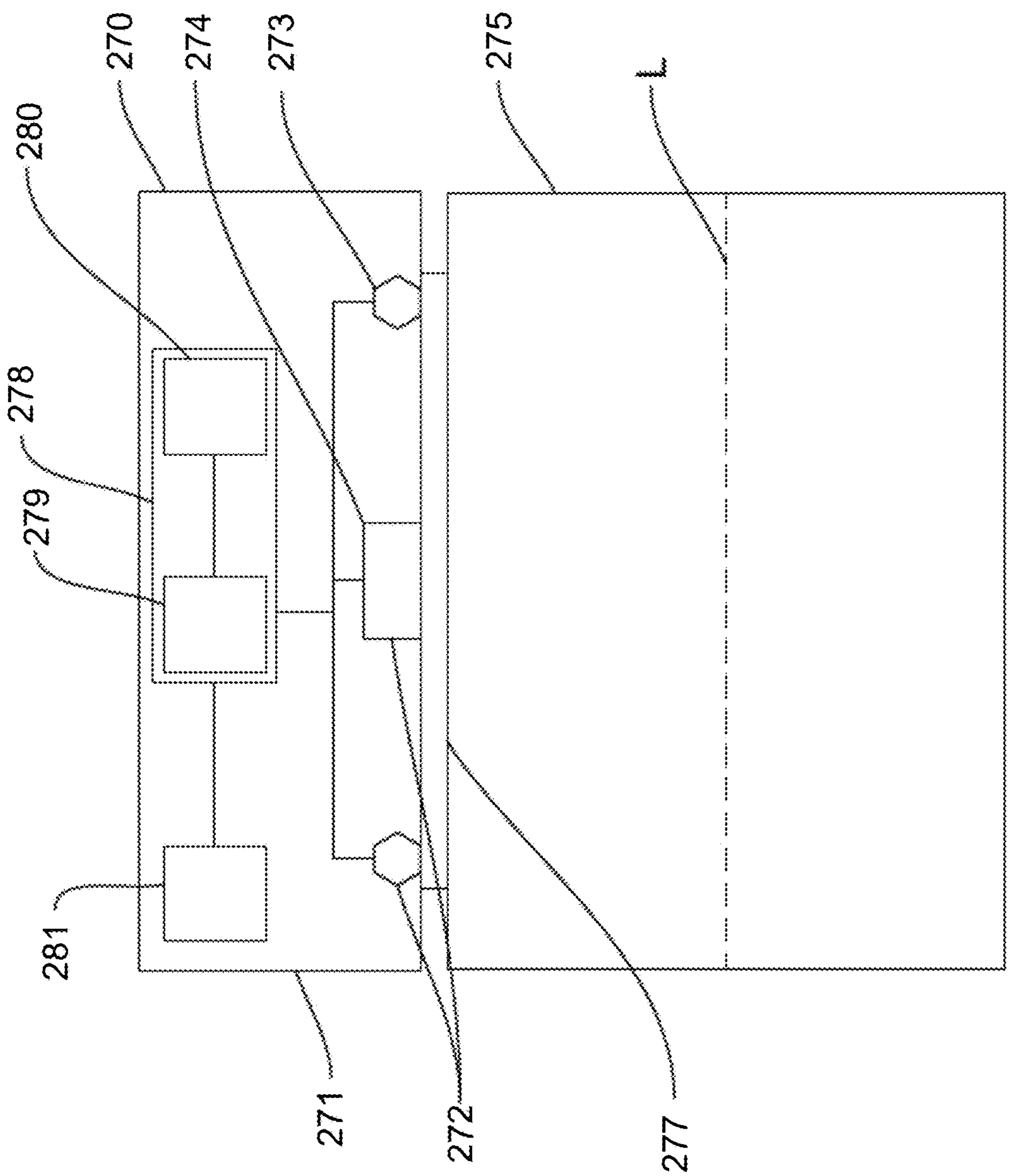


FIGURE 27

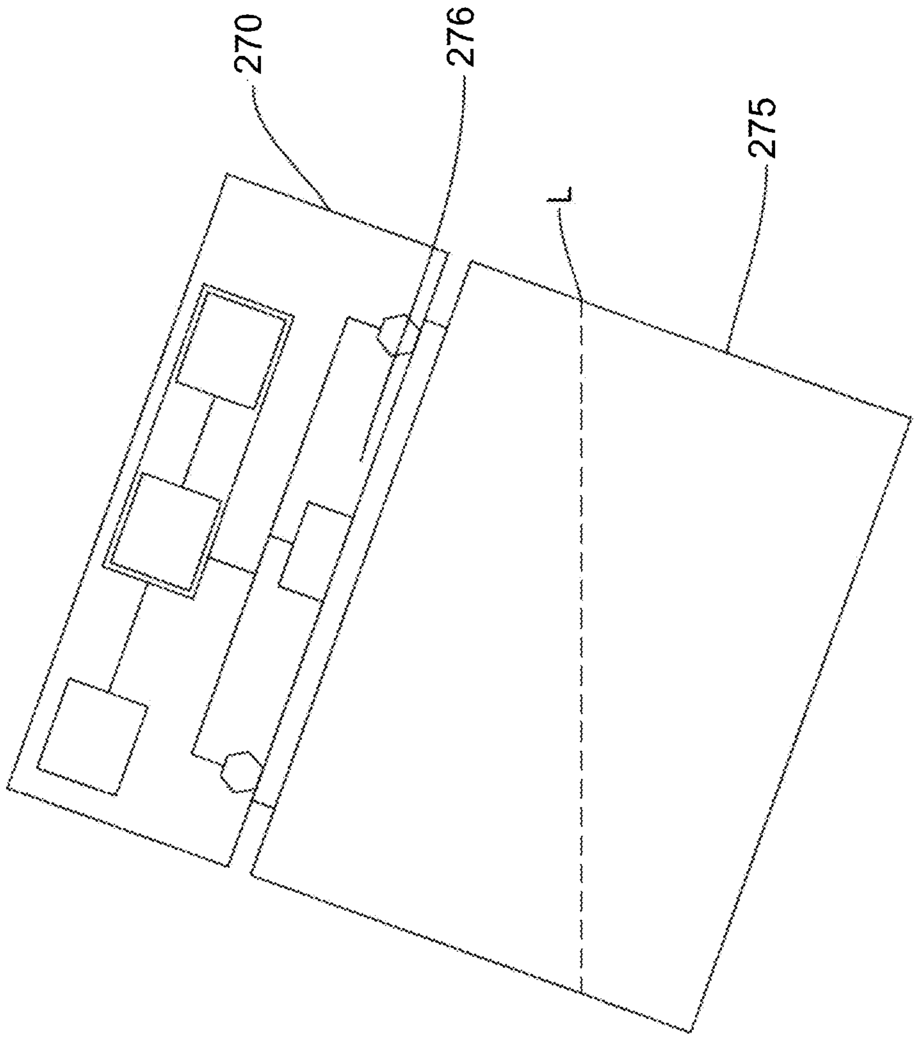


FIGURE 28

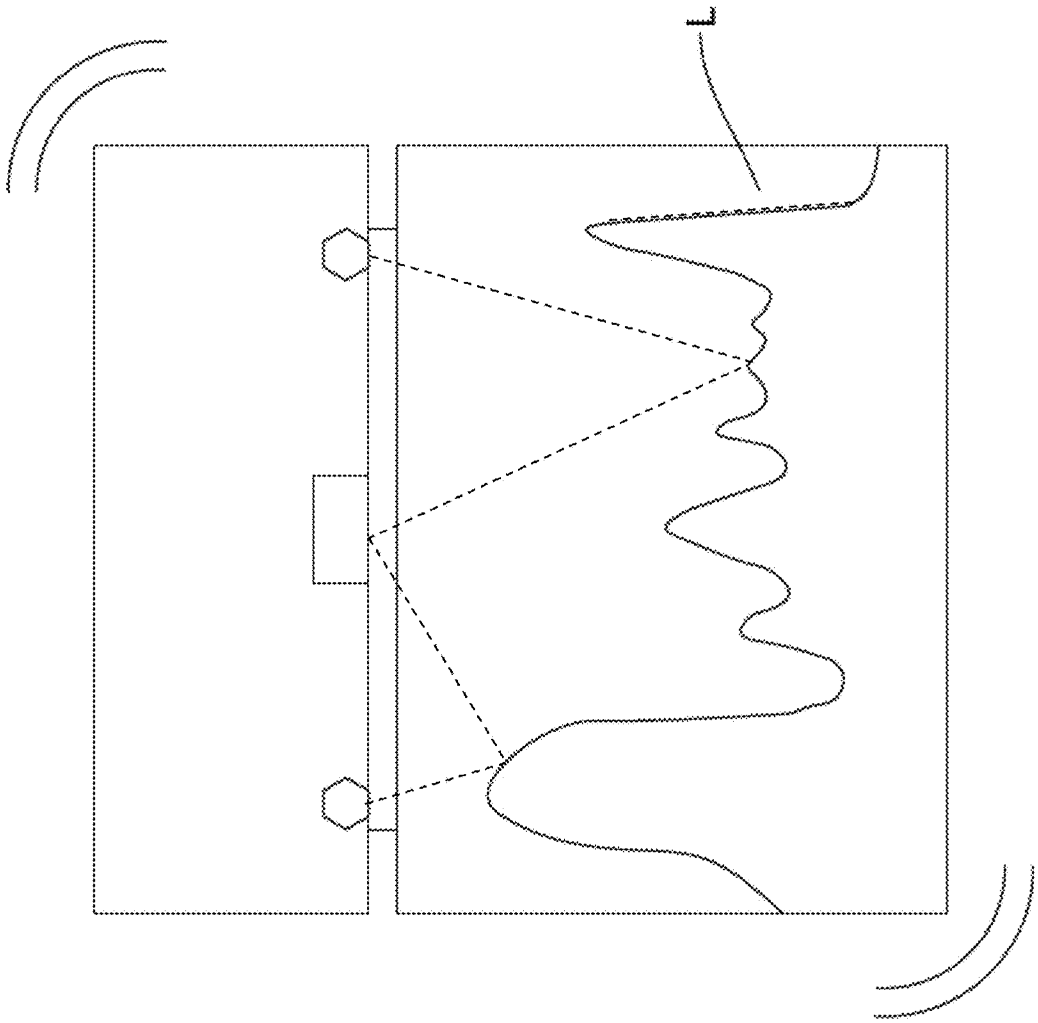


FIGURE 29

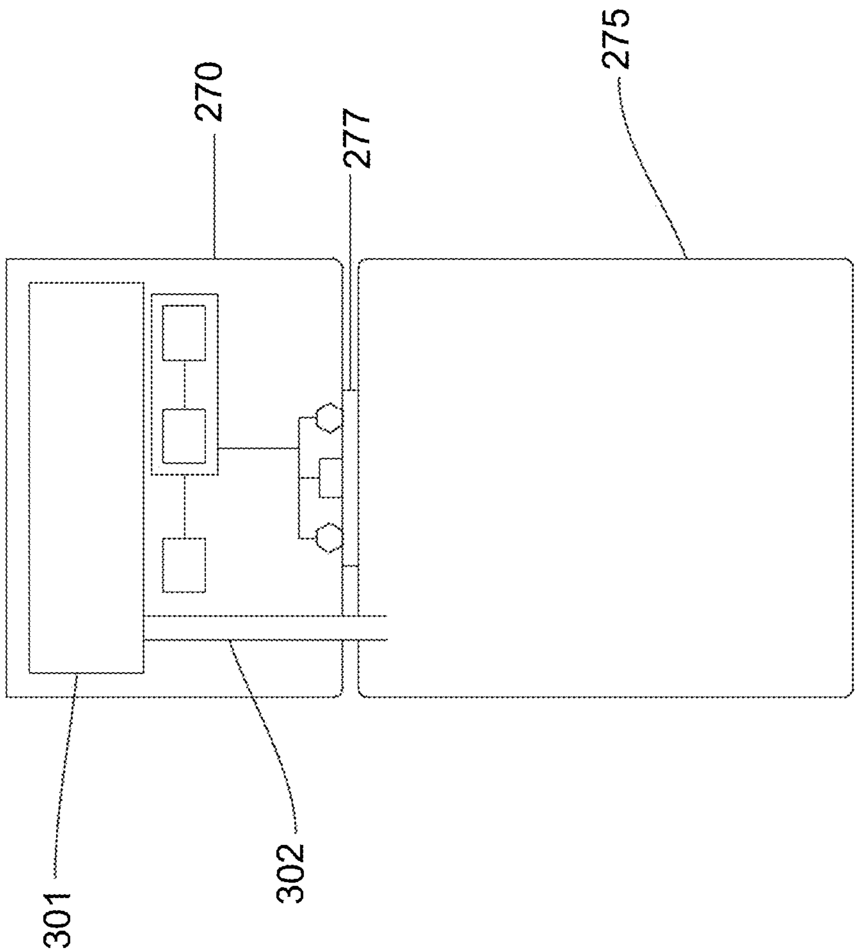


FIGURE 30

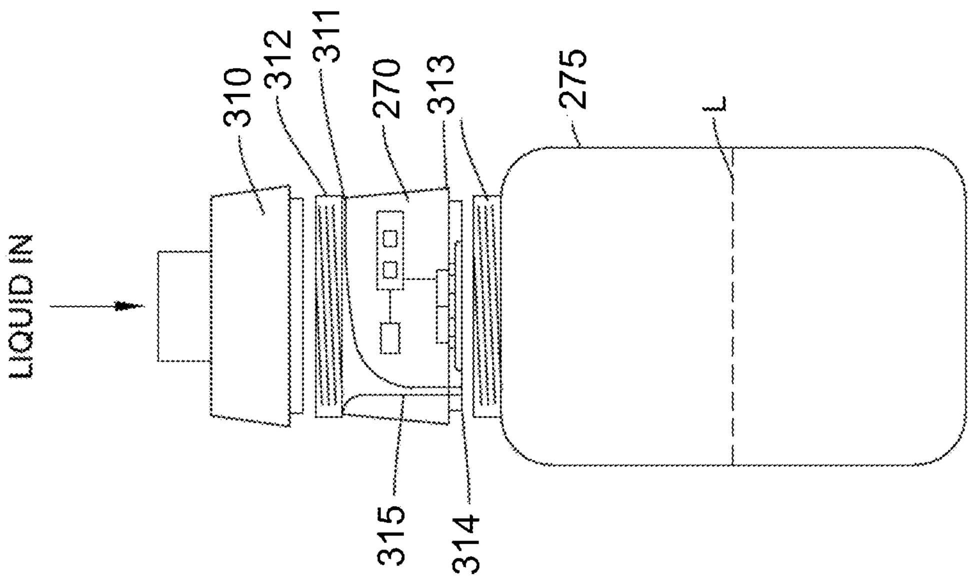


FIGURE 31

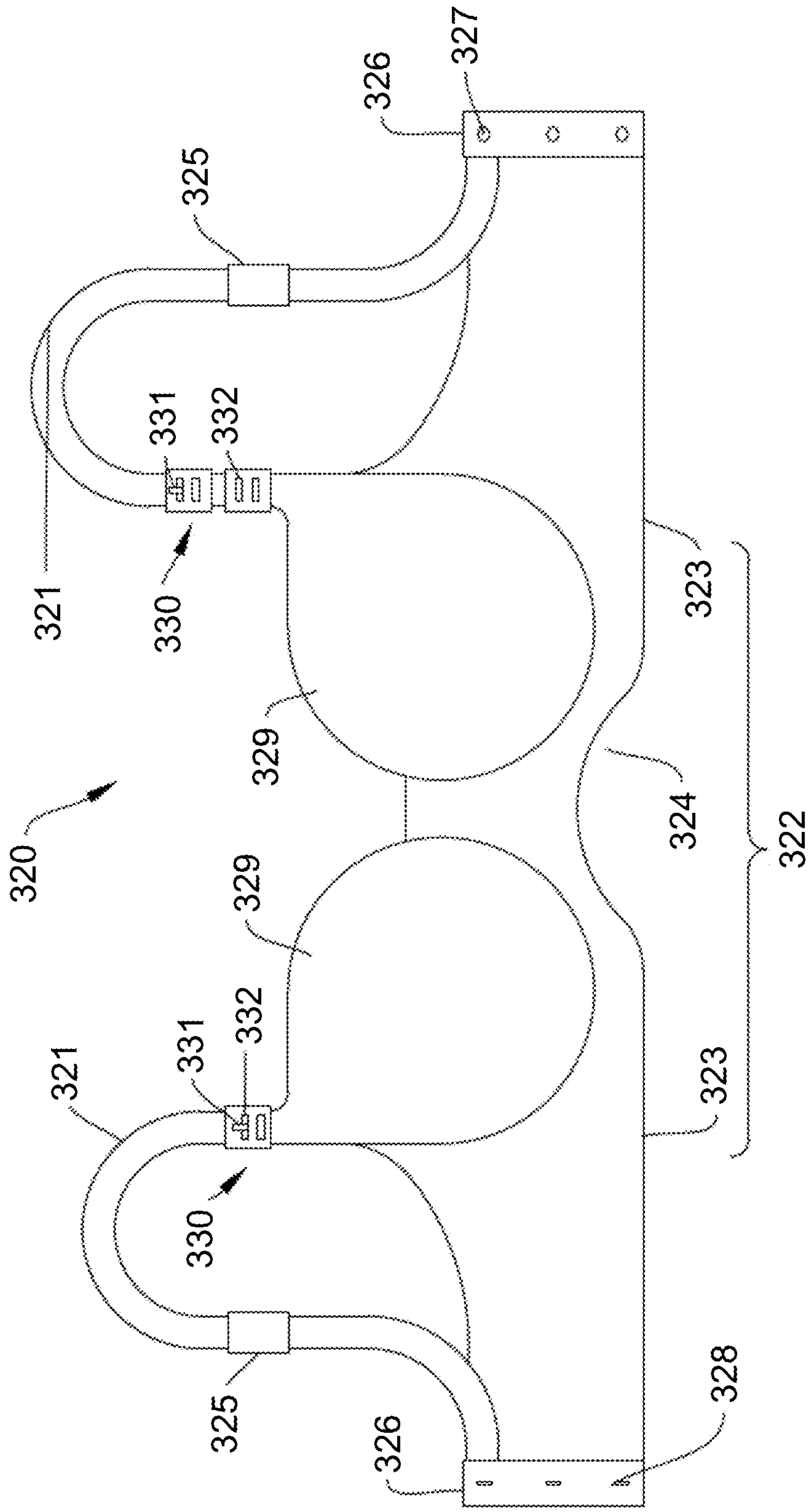

327
326
325
331
332
321
330
323
329
324
322
320
329
332
331
321
323
330
325
326
328

FIGURE 32

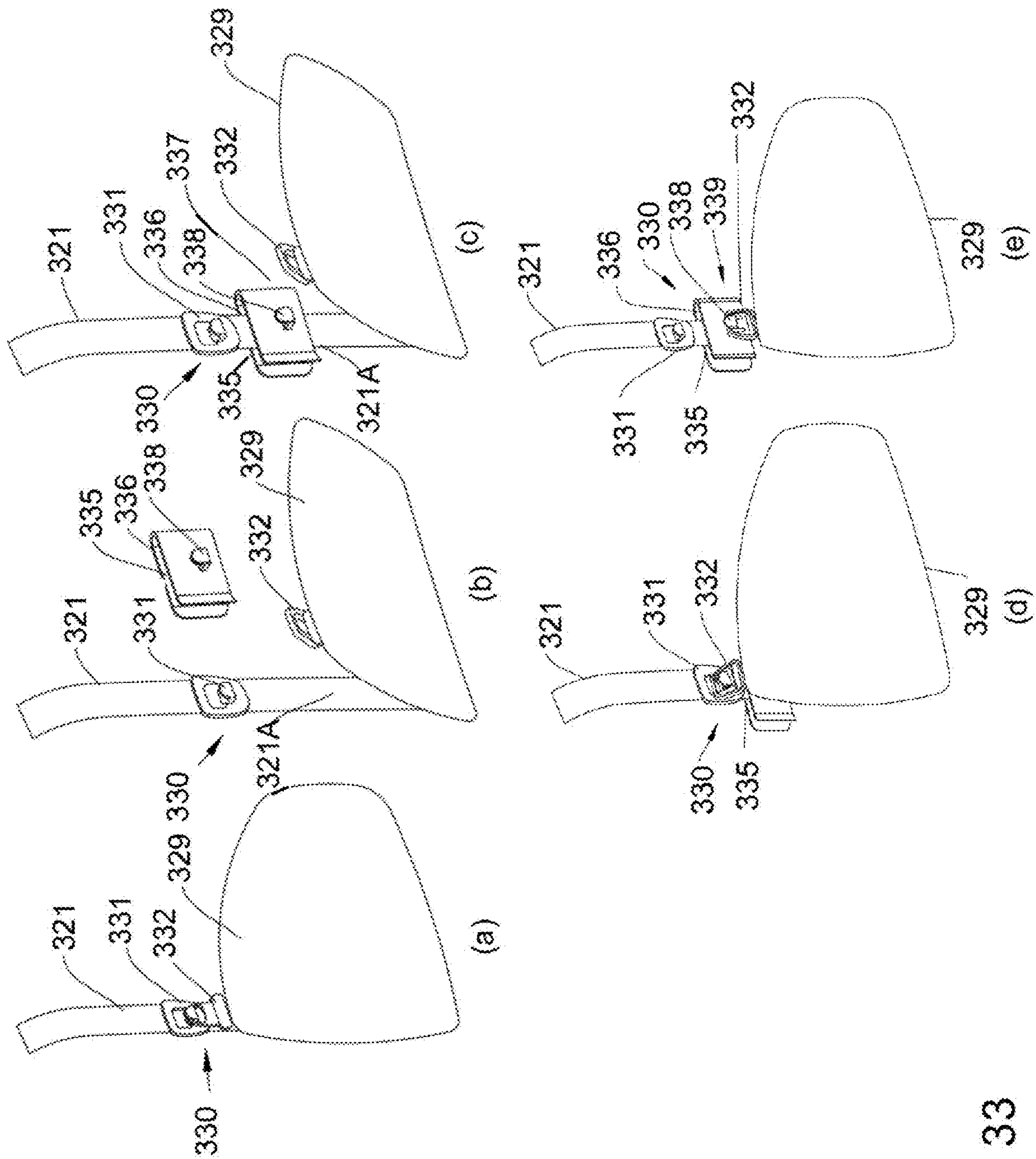


FIGURE 33

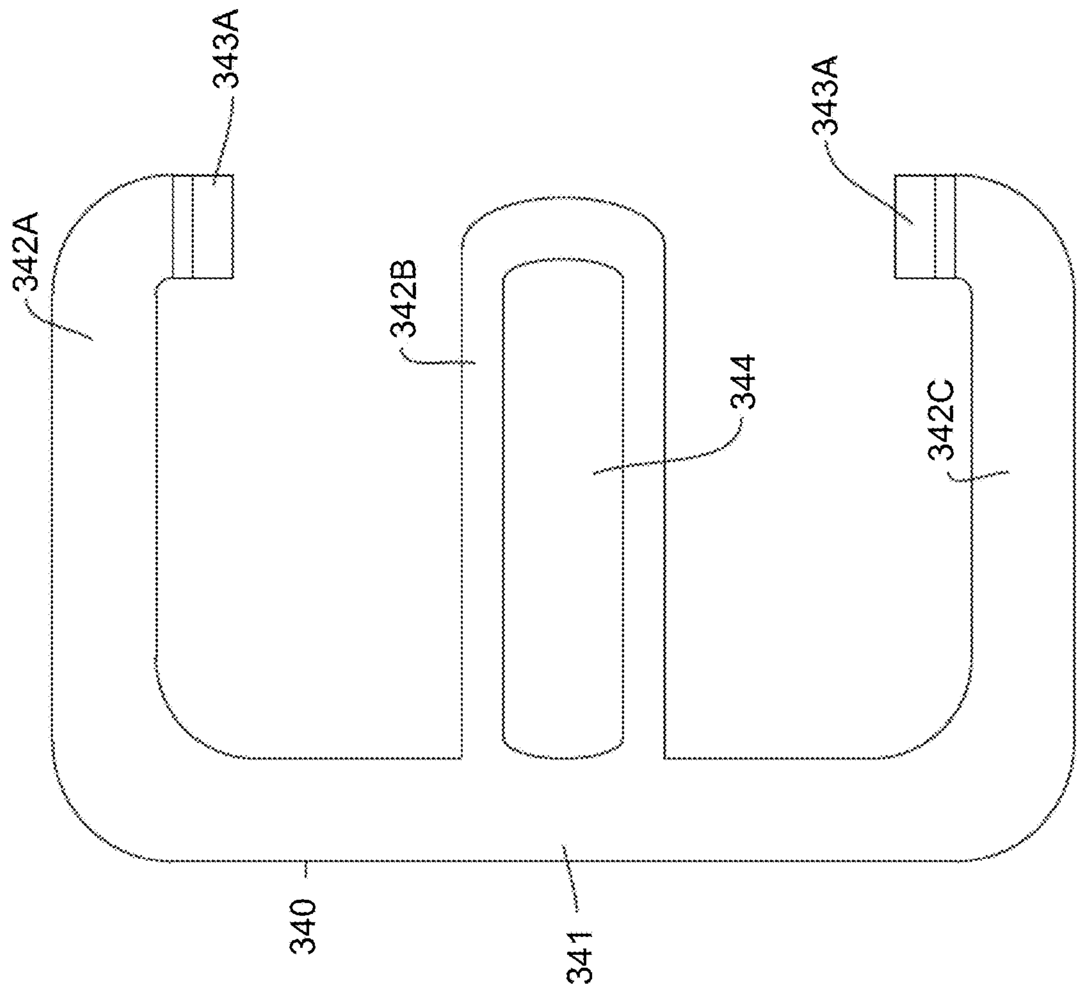


FIGURE 34

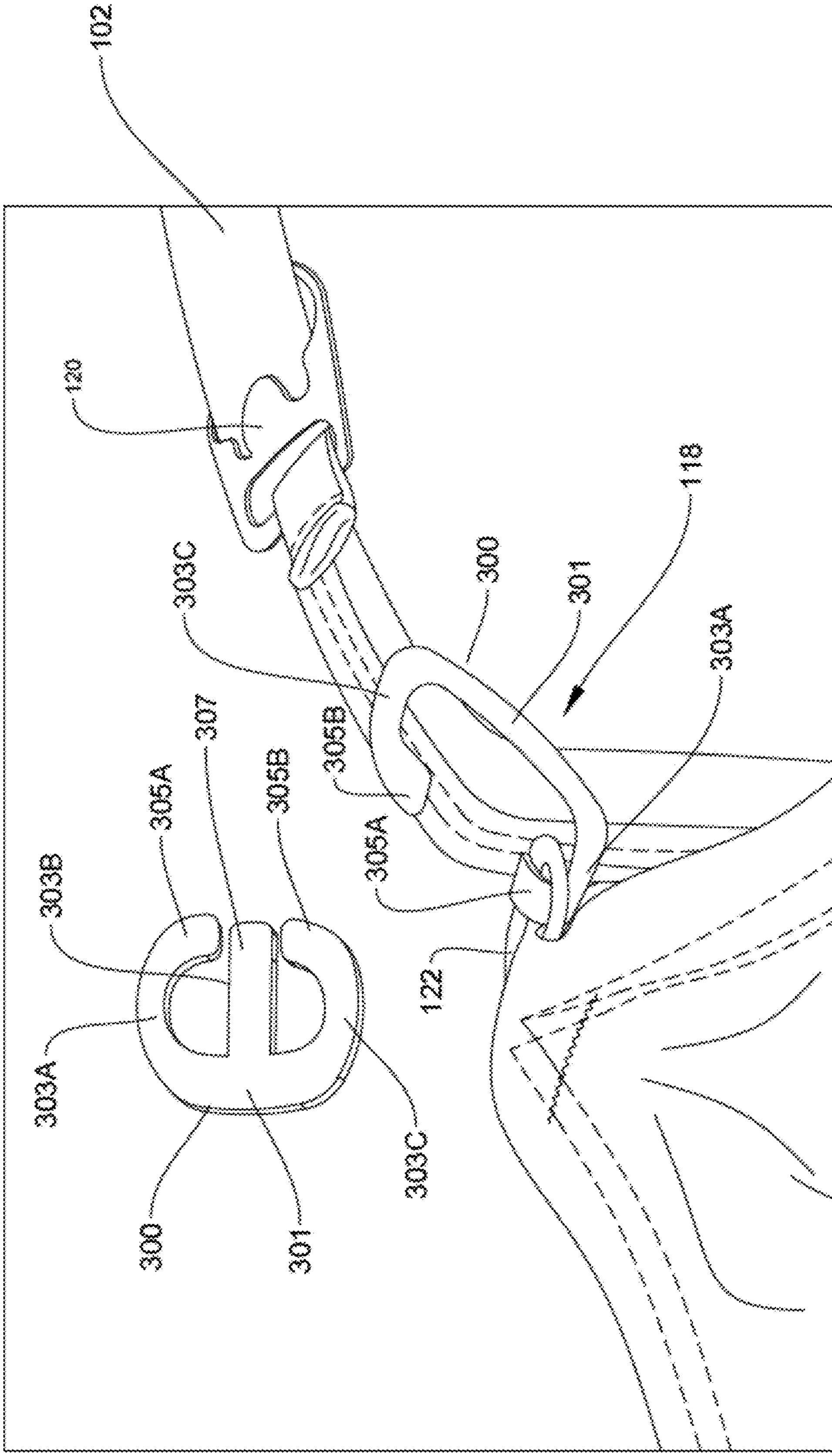


FIGURE 35

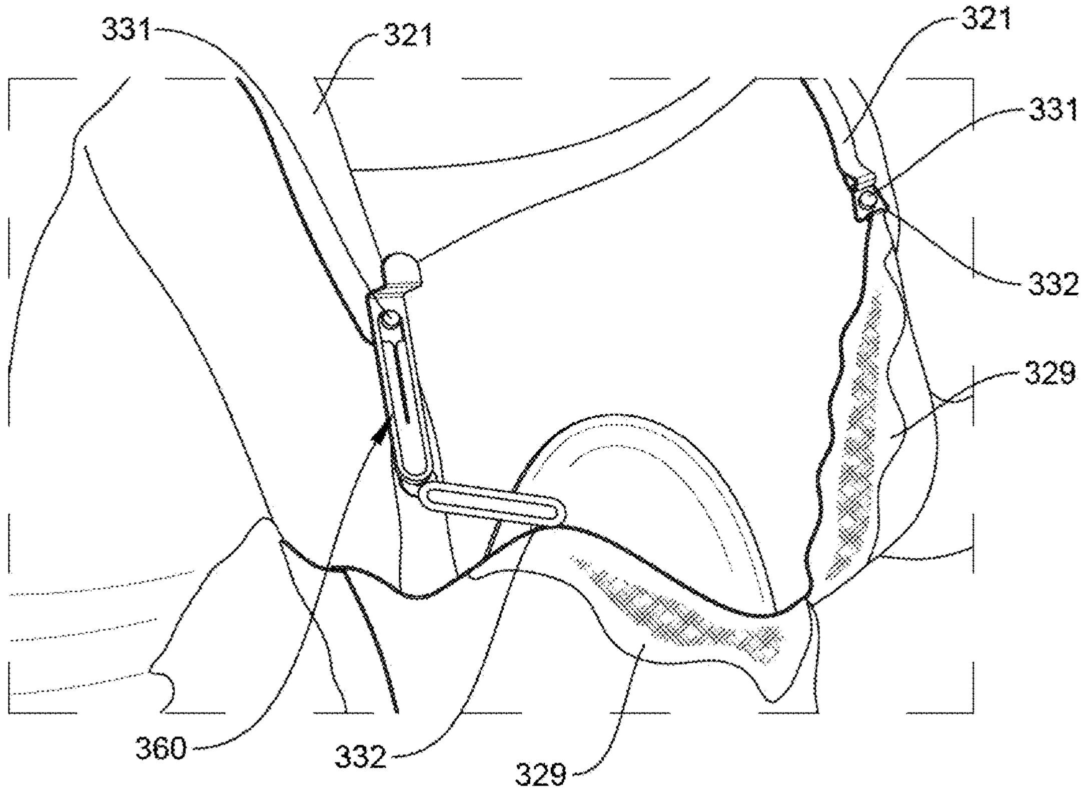


FIGURE 36

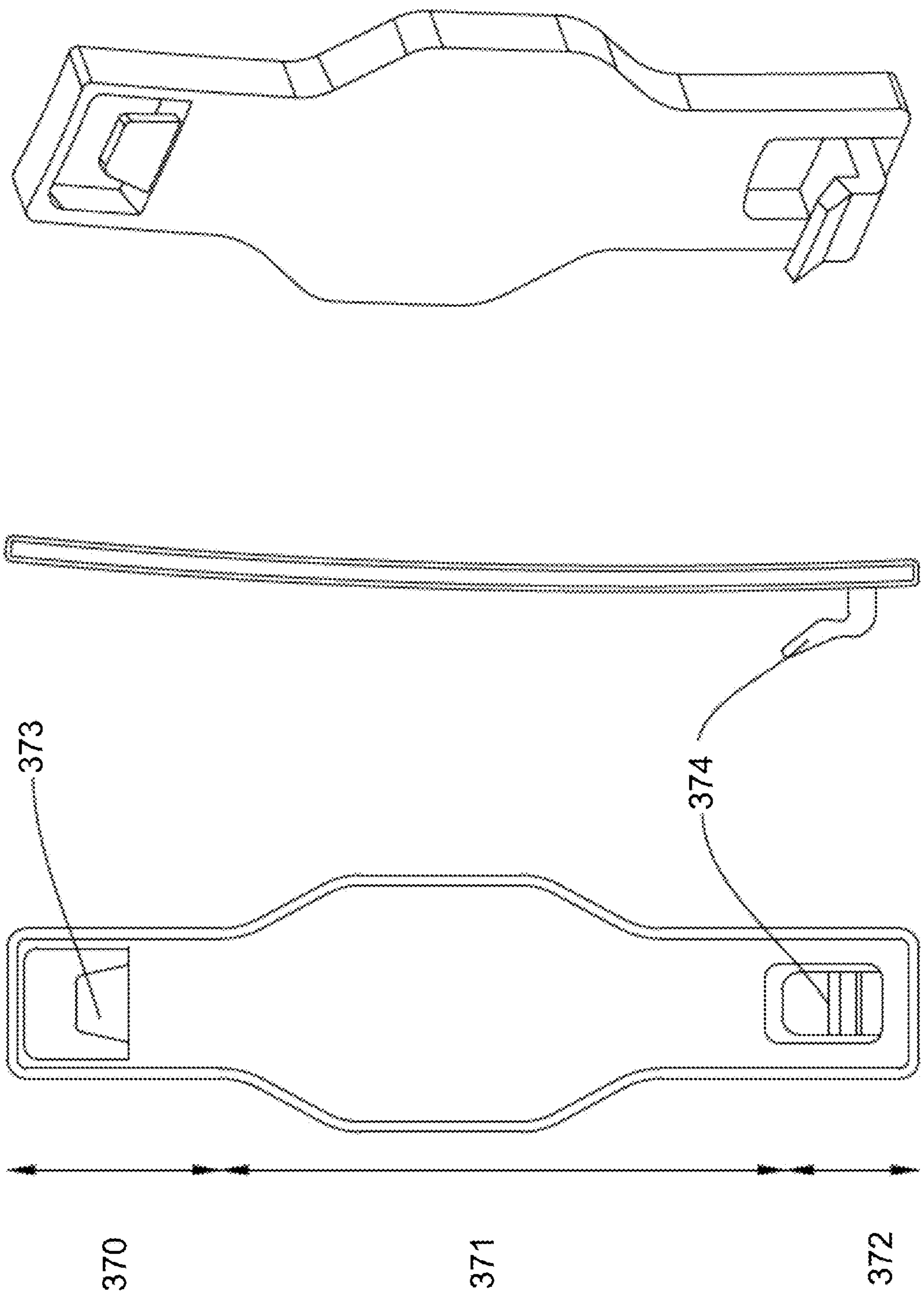


FIGURE 37

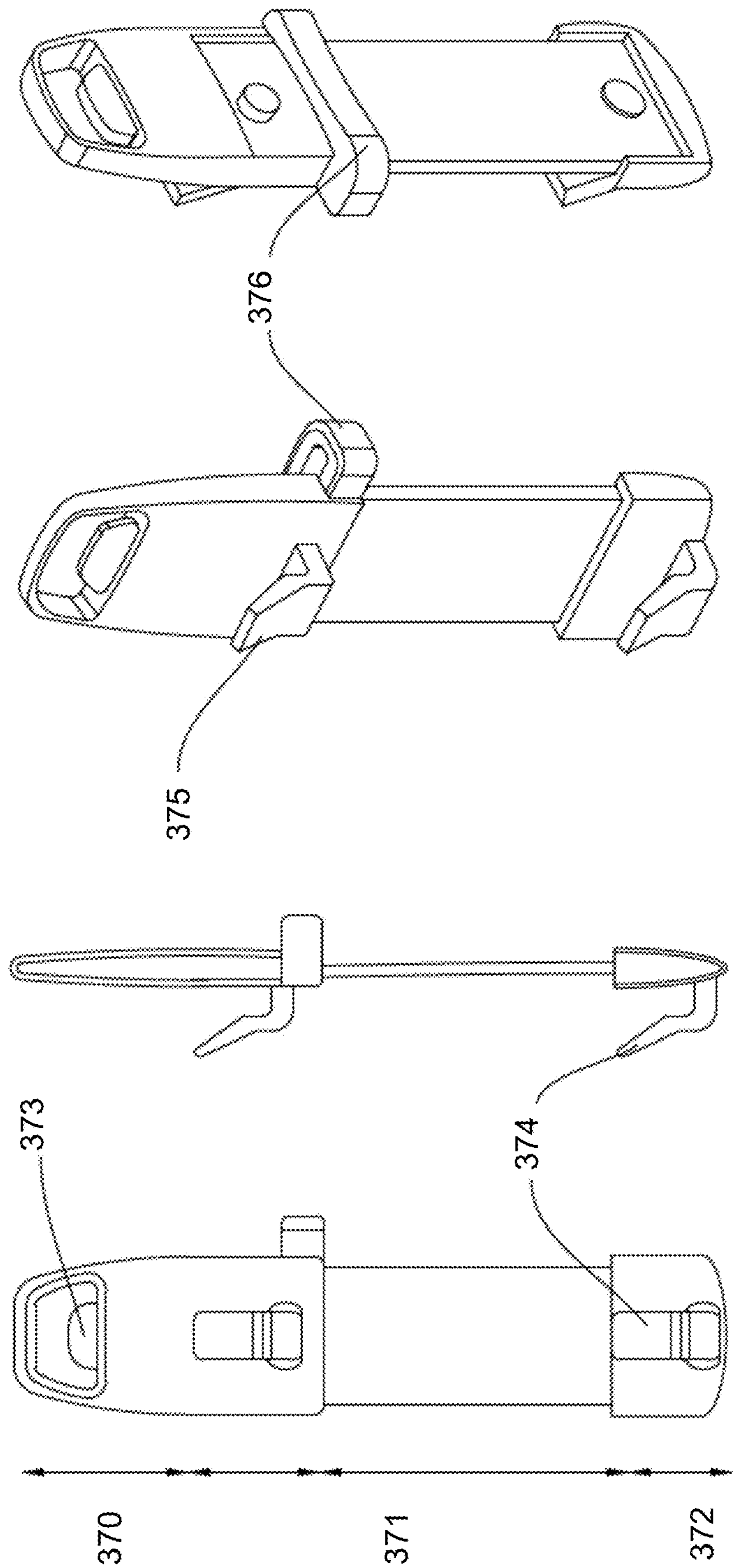


FIGURE 38

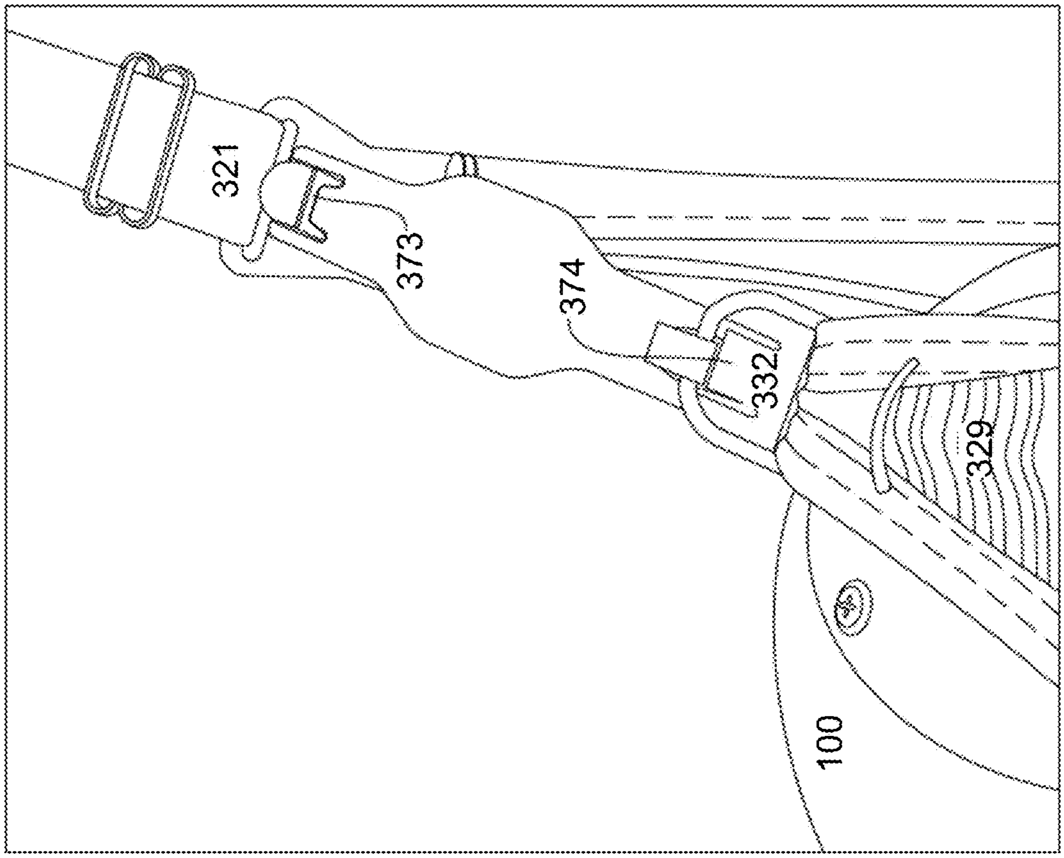


FIGURE 39

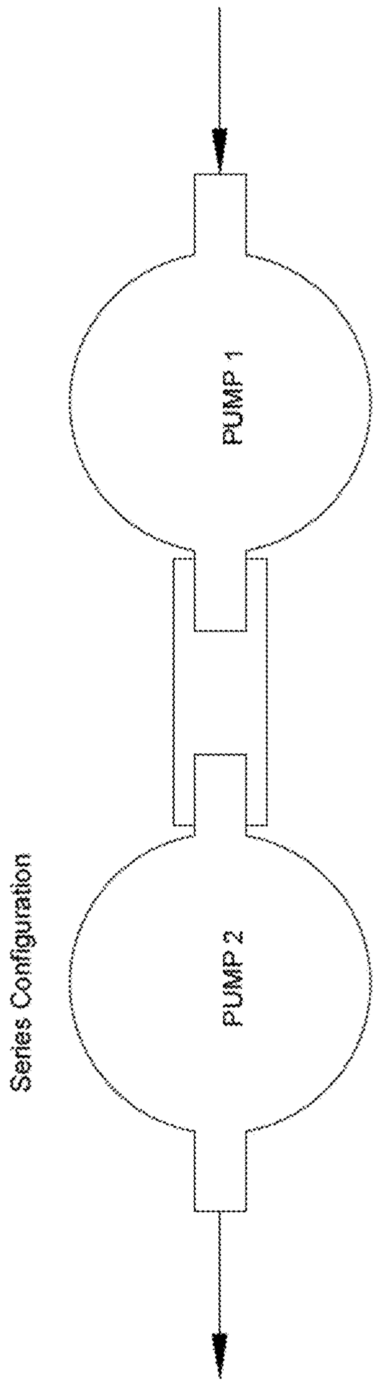


FIGURE 40

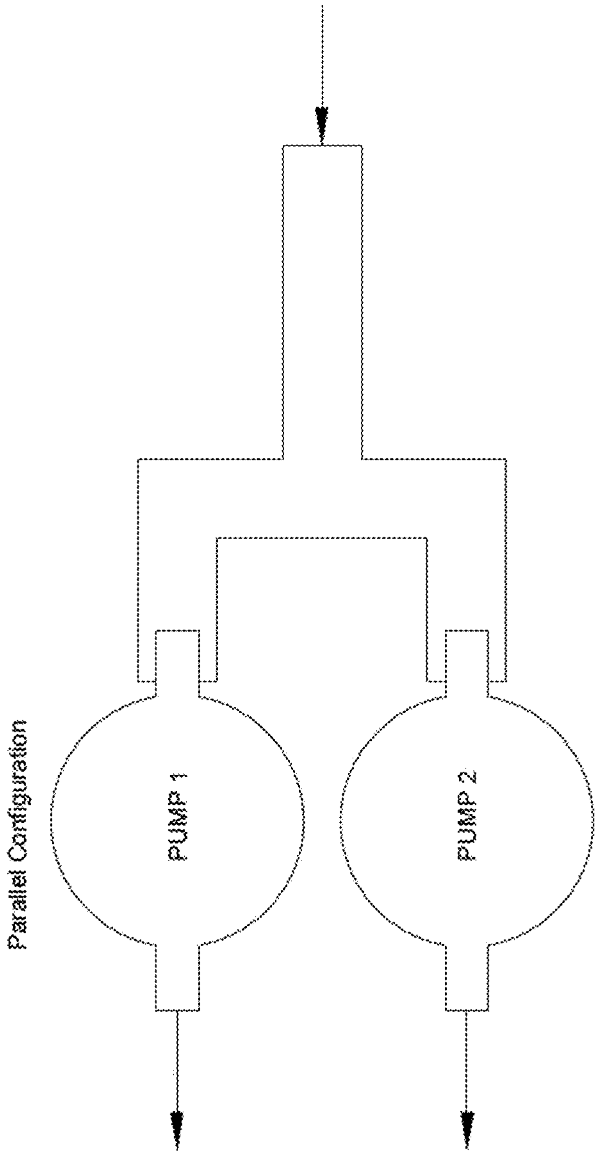


FIGURE 41

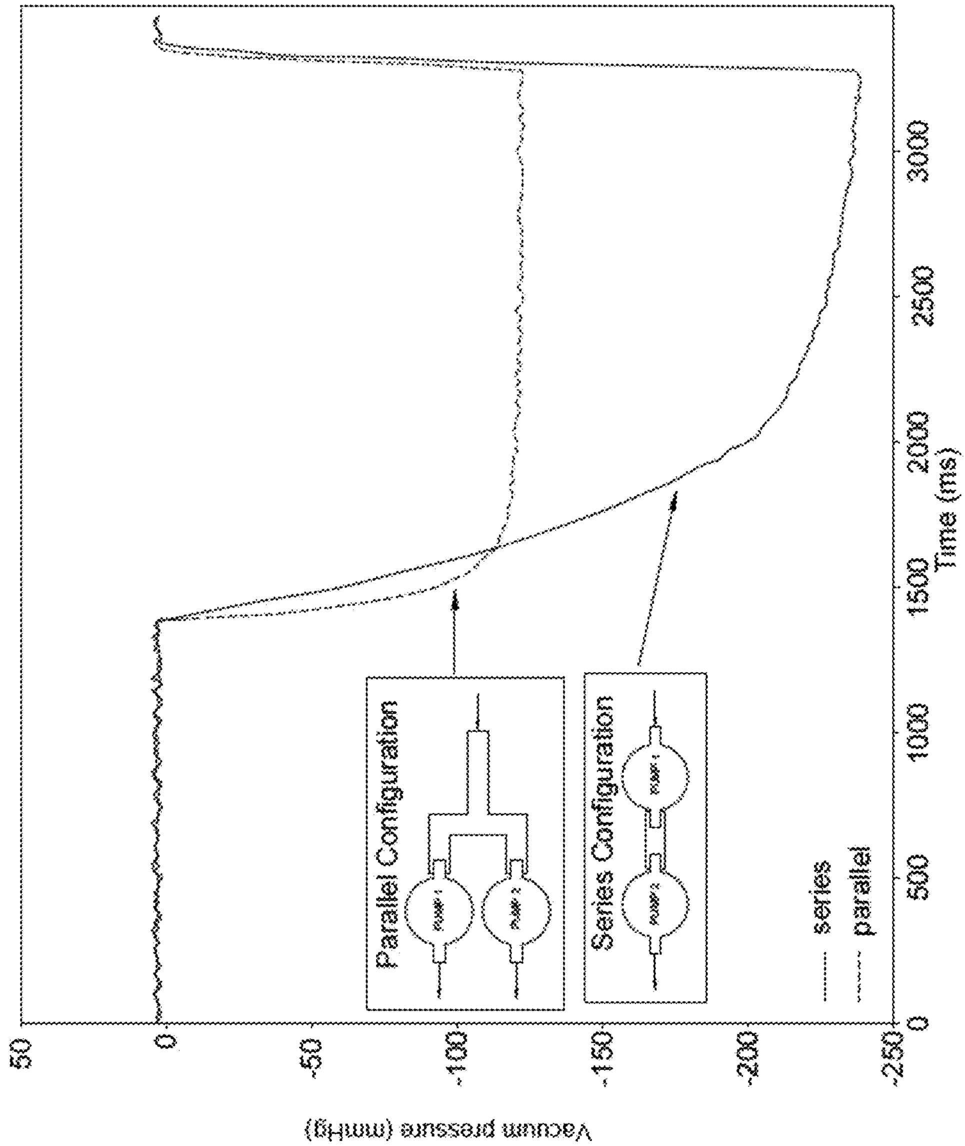

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
Time (ms)
0
500
1000
1500
2000
2500
3000
Parallel Configuration
Series Configuration
series
parallel

FIGURE 42

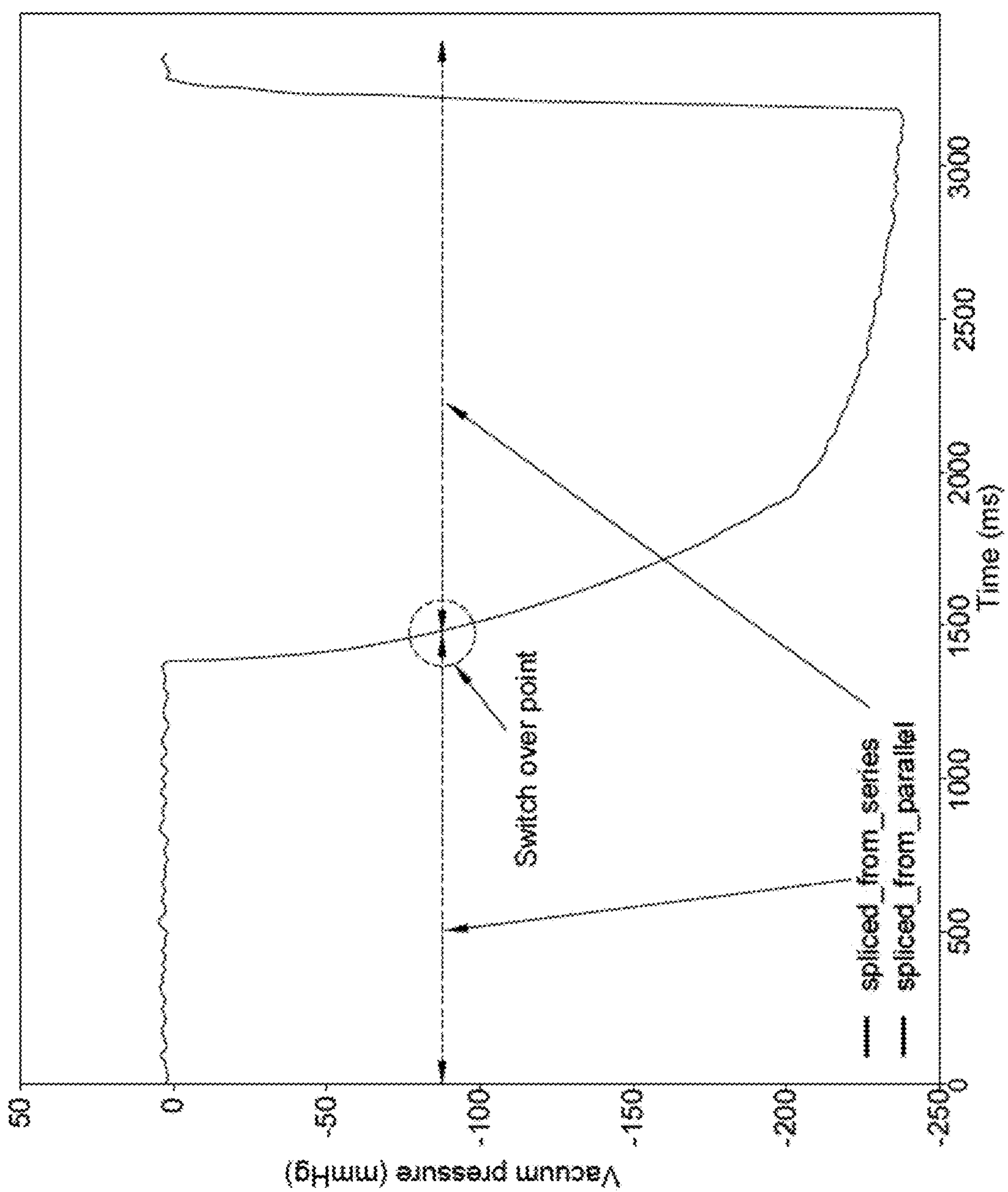

Vacuum pressure (mmHg)
50
0
-50
-100
-150
-200
-250
0
500
1000
1500
2000
2500
3000
Time (ms)
Switch over point
spliced_from_series
spliced_from_parallel

FIGURE 43

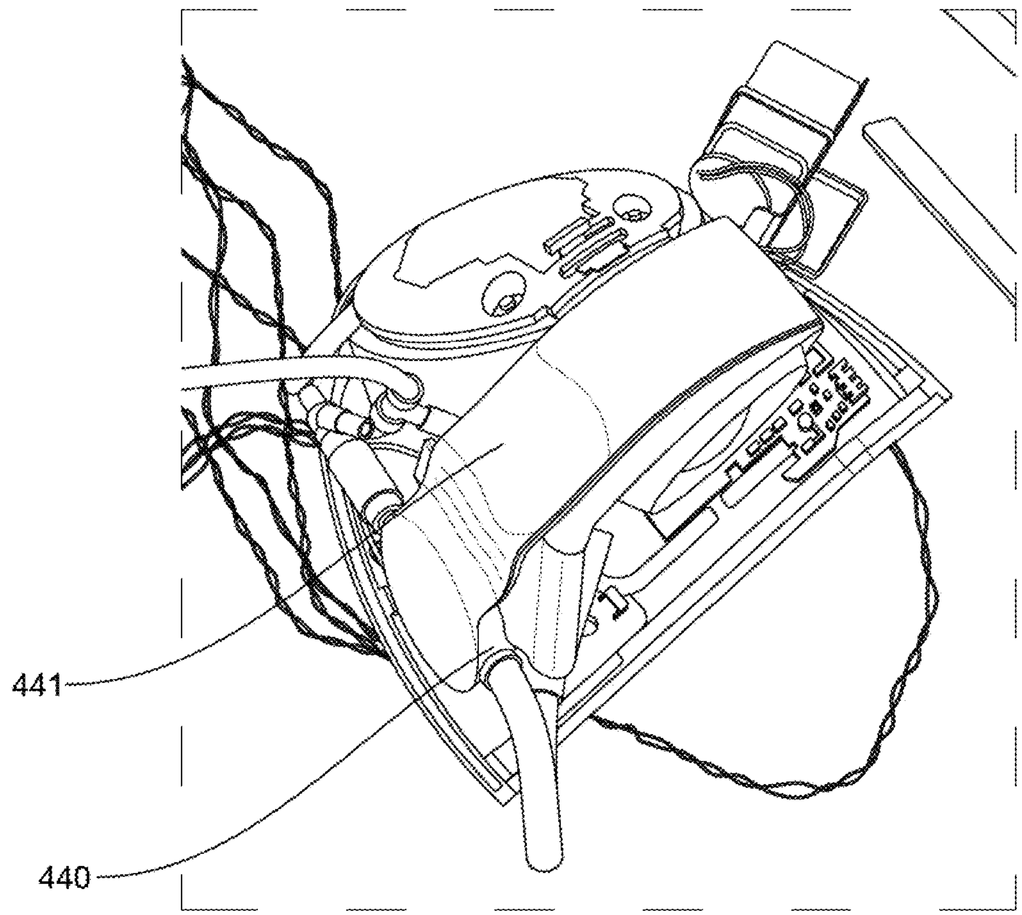


FIGURE 44

BREAST PUMP SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. application Ser. No. 17/181,057, filed on Feb. 22, 2021, which is a U.S. application Ser. No. 16/009,547, filed on Jun. 15, 2018, which is based on, and claims priority to, GB Application No. 1709561.3, filed Jun. 15, 2017; GB Application No. 1709564.7, filed on Jun. 15, 2017; GB Application No. 1709566.2, filed on Jun. 15, 2017; and GB Application No. 1809036.5, filed on Jun. 1, 2018, the entire contents of each of which being fully incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention relates to a breast pump system; one implementation of the system is a wearable, electrically powered breast pump system for extracting milk from a mother.

2. Description of the Prior Art

The specification of the present disclosure is broad and deep. We will now describe the prior art in relation to key aspects of the present disclosure.

Prior Art Related to Breast Pump Systems

A breast pump system is a mechanical or electro-mechanical device that extracts milk from the breasts of a lactating woman.

A typical breast pump design is as shown in WO 96/25187 A1. A large suction generating device is provided, which is freestanding. This is attached by air lines to one or two breast shields which engage with the user's breasts. A pressure cycle is applied from the suction generating device, via the air lines, to the breast shields. This generates a pressure cycle on the user's breasts to simulate the suction generated by a feeding child.

The suction generating device is a large component that connects to mains power to operate the pumps therein. Milk collection bottles are provided to store the expressed breast milk. In the system of WO 96/36298 A1 separate bottles are provided attached to each breast shield. A single bottle with tubing connecting to each breast shield may also be used. But for a mother to use this discretely, such as in an office environment, specialised bras must be used. In particular, breast-pumping bras which have a central slit, for the nipple tunnel of the breast shield to extend through, are typically used. The breast shield is held within the bra, with the suction generating device and milk bottle outside the bra.

The fundamental breast pump system has not significantly evolved from this approach, only minor technical improvements have been made.

However, these systems present a number of significant disadvantages. As the suction generating device is a large freestanding unit connected to mains power, the user may feel tethered to the wall. The known devices typically also require a specific user posture and undressing to function normally. This is obviously difficult for a user to do discretely, such as in an office setting. The known devices are also typically noisy, uncomfortable, and hard to clean.

Fully integrated wearable breast pump systems have begun to enter the market, such as described in US 2016 0206794 A1. In such pump systems, the suction source, power supply and milk container are contained in a single, wearable device; there is no need for bulky external components or connections. Such devices can be provided with a substantially breast shaped convex profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations. The internal breast shield is naturally convex to fit over a breast.

In US 2016 0206794 A1, when viewed from the front, the breast pump device has a 'tear-drop' rounded shape, fuller at its base than at its top. But it uses collapsible bags as milk collection devices. As the collection bag systems are collapsible, it can be difficult for a user to extract all of their milk from the bag, due to the small cut opening that is needed and the capillary action between the bonded plastic sheets that form the bag. This waste can be disheartening for the user, as this is food for their child. The bags are also not re-usable, so the user is required to purchase and maintain a stock of these. As well as presenting a recurring cost, if the user runs out of stock they are unable to use the product until more bags are purchased.

Furthermore, as a result of the collapsible bags, a complex and somewhat noisy pumping arrangement is necessary. In particular, the breast shield connects to a tube which is provided with compression units which "step" the expressed milk through the tube to the collection bag. This uses the breast milk as a hydraulic fluid to generate suction on the breast. In order to carry this out, a complex sequenced pulsing arrangement must be implemented.

In addition to these systems being particularly complex and wasteful, only a relatively small bag can be used. In US 2016 206794, approximately 110 ml (4 fluid ounces) of milk can be collected before the bag must be changed. While this may be sufficient for some users, others may produce much more milk in a session.

A further integrated wearable breast pump system is shown in US 2013 0023821 A1. In the third embodiment in this document, the breast pump system includes a motor driven vacuum pump and power source. An annular (or punctured disc) membrane is provided, with the flow path of the milk going through the centre of the annulus. The membrane is housed in separate housing and is sealed at its inner and outer edges. The breast shield has a small protrusion to engage with these housing components. However, the design of this breast pump system results in a number of problems. The use of an annular membrane, with the fluid flow path running through the opening of the annulus is undesirable as it results in a large and bulky device. There is therefore a need for improved integrated breast pump systems.

Prior Art Related to Liquid Measurement Systems

In the context of breast pump systems, it is useful to measure the quantity of expressed milk. One way to do this is to have a clear container for the breast pump, through which the level of expressed milk inside the container can be seen. However, viewing the milk bottle is not always pos-

sible, for example in a breast pump that collects milk while being worn inside a maternity bra.

An existing apparatus for detecting the level of liquid inside a container of a breast pump is that disclosed in US 2016/296681. In this apparatus, a sensing mechanism is provided at the top of a container, which detects droplets of liquid, specifically breast milk, entering the container. By detecting these droplets entering the container, the apparatus can determine the quantity of liquid which enters the container. In this apparatus, an accurate indication of the level of liquid in the container is reliant on the sensing mechanism being able to accurately record every droplet entering the container.

Particularly at times when liquid enters the container at a high flow rate, this accuracy cannot be guaranteed, leading to significant cumulative errors. An accurate indication of the level of liquid in the container in this apparatus is also reliant on the sensing mechanism always being on during the pumping process, so that power consumption of the sensing mechanism is correspondingly high.

In view of the above, there is the need for an improved way to determine the level of liquid inside a container connected to a breast pump.

Prior Art Related to Bra Clips

Many specialised bras (or brassieres) exist for maternity use and that facilitate nursing and/or breast pumping for milk collection, without the need to remove the bra itself. In a traditional nursing bra, this is achieved with the use of an at least partially detachable cup, which can be unhooked for feeding and/or pumping.

Further specialised bras are known which are provided with cut-out portions or slits which substantially align with the wearer's areola and nipple. Traditional breast pump systems comprise an elongate breast shield which extends away from the breast towards an external bottle and source of suction. The breast shield is arranged to extend through the cut-out portion or slit, with the collection bottle and pumping apparatus placed outside of the bra. These systems require the user to remove or unbutton any over-garments, and are uncomfortable when not pumping.

Integrated, wearable breast pump systems have begun to enter the market, such as previously noted US 2016 0206794 A1. In such pumps, the suction source, power supply and milk container are all in a single, wearable device, as noted above, without the need for bulky external components or connections. Such devices can be provided with a substantially breast shaped profile so as to fit within a user's bra for discrete pumping, as well as pumping on-the-go without any tethers to electrical sockets or collection stations.

Maternity (or nursing) bras such as disclosed in U.S. Pat. No. 4,390,024 A have partially detachable cups, with several hooks provided along the bra strap for attaching the cups to the strap. The cups can then be attached to different hooks in order to adjust the bra strap length. However, these attachment points are fixed. Additionally, this bra has been designed to accommodate the change in breast size before and after the feeding/pumping process. It is not designed to accommodate a breast pump. Accordingly, there is a need for a better system to accommodate integrated wearable breast pumps.

SUMMARY OF THE INVENTION

The invention is a wearable breast pump system including: a housing shaped at least in part to fit inside a bra; a piezo air-pump fitted in the housing and forming part of a closed loop system that drives a separate, deformable diaphragm to generate negative air pressure, that diaphragm being removably mounted on a breast shield.

BRIEF DESCRIPTION OF THE FIGURES

Aspects of the invention will now be described, by way of example(s), with reference to the following Figures, which each show features of various implementations of the invention including optional features that may be utilised:

FIG. **1** is a front view of an assembled breast pump system.

FIG. **2** is a rear view of the assembled breast pump system of FIG. **1**.

FIG. **3** is a front view of a partially disassembled breast pump system.

FIG. **4** is a rear view of the partially disassembled breast pump system of FIG. **3**.

FIG. **5** is a front view of a further partially disassembled breast pump system.

FIG. **6** is a rear view of the further partially disassembled breast pump system of FIG. **5**.

FIG. **7** is a front view of the breast pump system of FIG. **1**, with the outer shell translucent for ease of explanation.

FIG. **8** is a further front view of the breast pump system of FIG. **1**, with the front of the outer shell removed for ease of explanation.

FIG. **9** is a schematic view of a nipple tunnel for a breast shield.

FIG. **10** is a schematic of a pneumatic system for a breast pump system.

FIG. **11** is a schematic of an alternative pneumatic system for a breast pump system.

FIG. **12** is a schematic of a further alternative pneumatic system for a breast pump system.

FIG. **13** is a graph depicting measured pressure in the breast pump system of FIG. **12** over time.

FIG. **14** shows schematics for breast shield sizing and nipple alignment.

FIG. **15** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **16** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **17** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **18** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **19** shows a screenshot of an application running on a device connected to the breast pump system.

FIG. **20** shows a screenshot of an application running on a connected device.

FIG. **21** shows a screenshot of an application running on a connected device.

FIG. **22** shows a screenshot of an application running on a connected device.

FIG. **23** shows a screenshot of an application running on a connected device.

FIG. **24** shows a screenshot of an application running on a connected device.

FIG. **25** shows a screenshot of an application running on a connected device.

FIG. **26** shows a diagram of a breast pump sensor network,

FIG. **27** shows a sectional view of a device being used to determine the level of liquid in a container;

FIG. **28** shows a sectional view of the device and the container from FIG. **27** being used at a different orientation.

FIG. **29** shows a sectional view of the device and the container from FIG. **27** being used whilst undergoing acceleration.

FIG. **30** shows a sectional view of the device from FIG. **27** being used as part of a breast pump assembly.

FIG. **31** shows a sectional view of a device connected between a container and its lid, and which is operable to determine the level of liquid inside the container.

FIG. **32** depicts a prior art design for a maternity bra;

FIG. **33** depicts a clip and clasp being fitted to a maternity bra.

FIG. **34** depicts an alternative clip for adjustment of a maternity bra.

FIG. **35** depicts the alternative clip of FIG. **34**.

FIG. **36** depicts an alternative clip for adjustment of a maternity bra.

FIG. **37** depicts an alternative clip for adjustment of a maternity bra.

FIG. **38** depicts an alternative clip for adjustment of a maternity bra.

FIG. **39** depicts adjustment of the maternity bra of FIG. **37**.

FIG. **40** shows a configuration with two piezo pumps mounted in series.

FIG. **41** shows a configuration of two piezo pumps mounted in parallel.

FIG. **42** shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in series and mounted in parallel respectively.

FIG. **43** shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration.

FIG. **44** shows a figure of a pump including two piezo pumps in which each piezo pump is connected to a heat sink.

DETAILED DESCRIPTION

We will now describe an implementation of the invention, called the Elvie™ pump, in the following sections:

Section A: The Elvie™ Breast Pump System
Section B: An IR System
Section C: A Bra Clip
Section D: Piezo Pumps and Wearable Devices
Section A: The Elvie™ Breast Pump System
1. Elvie™ Breast Pump System Overview

An implementation of the invention, called the Elvie™ pump, is a breast pump system that is, at least in part, wearable inside a bra. The breast pump system comprises a breast shield for engagement with the user's breast, a housing for receiving at least a portion of the breast shield and a detachable rigid milk collection container attachable, in use, to a lower face of the housing and connected to the breast shield for collecting milk expressed by the user, with a milk-flow pathway defined from an opening in the breast shield to the milk collection container. The housing inside also includes a pump for generating a negative pressure in the breast shield, as well as battery and control electronics Unlike other wearable breast pumps, the only parts of the system that come into contact with milk in normal use are the breast shield and the milk container; milk only flows through the breast shield and then directly into the milk container. Milk does not flow through any parts of the housing at all, for maximum hygiene and ease of cleaning.

With reference to FIG. **1** and FIG. **2**, the assembled breast pump system **100** includes a housing **1** shaped to substantially fit inside a bra. The housing **1** includes one or more pumps and a rechargeable battery. The breast pump system includes two parts that are directly connected to the housing **1**: the breast shield **7** and a milk container **3**. The breast shield **7** and the milk container **3** are directly removable or attachable from the housing **1** in normal use or during normal dis-assembly (most clearly shown in FIG. **5**). All other parts that are user-removable in normal use or during normal dis-assembly are attached to either the breast shield **7** or the milk container **3**. The breast shield **7** and milk container **3** may be removed or attached for example using a one click or one press action or a push button or any other release mechanism. Audible and/or haptic feedbacks confirm that the pump is properly assembled.

The modularity of the breast pump allows for easy assembly, disassembly and replacement of different parts such as the breast shield and milk collection container. This also allows for different parts of the pump to be easily washed and/or sterilised. The breast shield and bottle assembly, both of which are in contact with milk during pumping, may therefore be efficiently and easily cleaned; these are the only two items that need to be cleaned; in particular, the housing does not need to be cleaned.

The housing **1**, breast shield **7** that is holding a flexible diaphragm, and milk container **3** attach together to provide a closed-loop pneumatic system powered by piezoelectric pumps located in the housing **1**. This system then applies negative pressure directly to the nipple, forms an airtight seal around the areola, and provides a short path for expressed milk to collect in an ergonomically shaped milk container **3**.

The different parts of the breast shield system are also configured to automatically self-seal under negative pressure for convenience of assembly and disassembly and to reduce the risk of milk spillage. Self-sealing refers to the ability of sealing itself automatically or without the application of adhesive, glue, or moisture (such as for example a self-sealing automobile tire or self-sealing envelopes). Hence once the breast pump system is assembled it sell-seals under its assembled condition without the need to force seals into interference fits to create sealed chambers. A degree of interference fitting is usual however, but is not the predominating attachment mechanism. Self-sealing enables simple components to be assembled together with a light push: for example, the diaphragm just needs to be placed lightly against the diaphragm housing; it will self-seal properly and sufficiently when the air-pump applies sufficient negative air-pressure. The diaphragm itself self-seals against the housing when the breast shield is pushed into the housing. Likewise, the breast shield self-seals against the milk container when the milk container is pushed up to engage the housing. This leads to simple and fast assembly and disassembly, making it quick and easy to set the device up for use, and to clean the device after a session.

Self-sealing has a broad meaning and may also relate to any, wholly or partly self-energising seals. It may also cover any interference seals, such as a press seal or a friction seal, which are achieved by friction after two parts are pushed together.

Whilst one particular embodiment of the invention's design and a specific form of each of the parts of the breast pump system is detailed below, it can be appreciated that the overall description is not restrictive, but an illustration of topology and function that the design will embody, whilst not necessary employing this exact form or number of discrete parts.

The breast pump system **100** comprises a housing **1** and a milk collection container (or bottle) **3**. The housing **1** (including the one or more pumps and a battery) and the container **3** are provided as a unit with a convex outer surface contoured to fit inside a bra. The milk collection container **3** is attached to a lower face **1**A of the housing **1** and forms an integral part of the housing when connected, such that it can be held comfortably inside a bra. While the breast pump **100** may be arranged to be used with just the right or the left breast specifically, the breast pump **100** is preferably used with both breasts, without modification. To this end, the outer surfaces of the breast pump **100** are preferably substantially symmetrical.

Preferably, the width of the complete breast pump device (housing **1** and milk container **3**) is less than 110 mm and the height of the complete breast pump device is less than 180 mm.

Overall, the breast pump system **100** gives discrete and comfortable wear and use. The system weighs about 224 grams when the milk container is empty, making it relatively lighter as compared to current solutions; lightness has been a key design goal from the start, and has been achieved through a lightweight piezo pump system and engineering design focused on minimising the number of components.

The breast pump system **100** is small enough to be at least in part held within any bra without the need to use a specialized bra, such as a maternity bra or a sports bra. The rear surface of the breast pump is also concave so that it may sit comfortably against the breast. The weight of the system has also been distributed to ensure that the breast pump is not top heavy, ensuring comfort and reliable suction against the breast. The centre of gravity of the pump system is, when the container is empty, substantially at or below the horizontal line that passes through the filling point on the breast shield, so that the device does not feel top-heavy to a person while using the pump.

Preferably, when the container is empty, the centre of gravity is substantially at or below the half-way height line of the housing so that the device does not feel top-heavy to a user using the pump.

The centre of gravity of the breast pump, as depicted by FIG. **1**, is at around 60 mm high on the centreline from the base of the breast pump when the milk container is empty. During normal use, and as the milk container gradually receives milk, the centre of gravity lowers, which increases the stability of the pump inside the bra. It reduces to around 40 mm high on the centreline from the base of the breast pump when the milk container is full.

The centre of gravity of the breast pump is at about 5.85 mm below the centre of the nipple tunnel when the milk container is empty, and reduced to about 23.60 mm below the centre of the nipple tunnel when the milk container is full. Generalizing, the centre of gravity should be at least 2 mm below the centre of the nipple tunnel when the container is empty.

The breast pump **100** is further provided with a user interface **5**. This may take the form of a touchscreen and/or physical buttons. In particular, this may include buttons, sliders, any form of display, lights, or any other componentry necessary to control and indicate use of the breast pump **100**. Such functions might include turning the breast pump **100** on or off, specifying which breast is being pumped, increasing or decreasing the peak pump pressure. Alternatively, the information provided through the user interface **5** might also be conveyed through haptic feedback, such as device vibration, driven from a miniature vibration motor within the pump housing **1**.

In the particular embodiment of the Figures, the user interface **5** comprises power button **5**A for turning the pump on and off. The user interface **5** further comprises pump up button **5**B and pump down button **5**C. These buttons adjust the pressure generated by the pump and hence the vacuum pressure applied to the user's breast. In preferable embodiments, the pump up button **5**B could be physically larger than the pump down button **5**C. A play/pause button **5**D is provided for the user to interrupt the pumping process without turning the device off.

The user interface **5** further comprises a breast toggle button **5**E for the user to toggle a display of which breast is being pumped. This may be used for data collection, e.g. via an application running on a connected smartphone; the app sends data to a remote server, where data analysis is undertaken (as discussed in more detail later), or for the user to keep track of which breast has most recently been pumped. In particular, there may be a pair of LEDs, one to the left of the toggle button **5**E and one to the right. When the user is pumping the left breast, the LED to the right of the toggle button **5**E will illuminate, so that when the user looks down at the toggle it is the rightmost LED from their point of view that is illuminated. When the user then wishes to switch to the right breast, the toggle button can be pressed and the LED to the left of the toggle button **5**E, when the user looks down will illuminate. The connected application can automatically track and allocate how much milk has been expressed, and when, by each breast.

The breast pump system also comprises an illuminated control panel, in which the level of illumination can be controlled at night or when stipulated by the user. A day time mode, and a less bright night time mode that are suitable to the user, are available. The control of the illumination level is either implemented in hardware within the breast pump system itself or in software within a connected device application used in combination with the breast pump system.

As depicted in FIG. **1**, the housing **1** and milk collection container **3** form a substantially continuous outer surface, with a generally convex shape. This shape roughly conforms with the shape of a 'tear-drop' shaped breast. This allows the breast pump **100** to substantially fit within the cup of a user's bra. The milk collection container **3** is retained in attachment with the housing **1** by means of a latch system, which is released by a one-click release mechanism such as a push button **2** or any other one-handed release mechanism. An audible and/or haptic feedback may also be used to confirm that the milk collection container **3** has been properly assembled.

The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting an additional 2 cm difference. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc. In preferred embodiments, the breast pump **100** of the present invention corresponds to an increase of between 3 or 4 cup sizes of the user according to EN 13402.

A plane-to-plane depth of the breast pump can also be defined. This is defined as the distance between two parallel planes, the first of which is aligned with the innermost point of the breast pump **100**, and the second of which is aligned with the outermost point of the breast pump **100**. This distance is preferably less than 100 mm.

FIG. **2** is a rear view of the breast pump **100** of FIG. **1**. The inner surface of the housing **1** and milk collection container **3** are shown, along with a breast shield **7**. The housing **1**,

milk collection container **3** and breast shield **7** form the three major subcomponents of the breast pump system **100**. In use, these sub-components clip together to provide the functioning breast pump system **100**. The breast shield **7** is designed to engage with the user's breast, and comprises a concave inner flange **7**A which contacts the breast. To allow the breast pump **100** to be used on either of the user's breasts, the breast shield **7** is preferably substantially symmetrical on its inner flange **7**A.

The inner flange **7**A is substantially oval-shaped. While the inner flange **7**A is concave, it is relatively shallow such that it substantially fits the body form of the user's breast. In particular, when measured side-on the inner-most point of the flange **7**A and the outer-most point may be separated by less than 25 mm. By having a relatively shallow concave surface, the forces applied can be spread out over more surface area of the breast. The flatter form also allows easier and more accurate location of the user's nipple. In particular, the flange **7**A of the breast shield **7** may extend over the majority of the inner surface of the housing **1** and milk collection container **3**. Preferably, it may extend over 80% of this surface. By covering the majority of the inner surface, the breast shield is the only component which contact's the wearer's breast. This leaves fewer surfaces which require thorough cleaning as it reduces the risk of milk contacting a part of the device which cannot be easily sterilized. Additionally, this also helps to disperse the pressure applied to the user's breast across a larger area.

The breast shield **7** substantially aligns with the outer edge **1**B of the housing **1**. The milk collection container **3** may be provided with an arcuate groove for receiving a lower part of the breast shield **7**. This is best shown in later Figures. In the assembled arrangement of FIGS. **1** and **2**, the inner surface of the breast pump **100** is substantially continuous.

The breast shield **7** comprises a shield flange for engaging the user's breast, and an elongate nipple tunnel **9**) aligned with the opening and extending away from the user's breast. Breast shield nipple tunnel **9** extends from a curved section **7**B in the breast shield **7**. In preferable embodiments the nipple tunnel **9** is integral with the breast shield **7**. However, it is appreciated that separate removable/interchangeable nipple tunnels may be used. Curved section **7**B is positioned over the user's nipple and areola in use. The breast shield **7** forms an at least partial seal with the rest of the user's breast around this portion, under the negative air pressure created by an air-pressure pump.

This breast shield nipple tunnel **9** defines a milk-flow path from the inner surface of the breast shield **7**A, through the breast shield nipple tunnel **9** and into the milk collection container **3**. The breast shield nipple tunnel **9** is preferably quite short in order to minimise the length of the milk-flow path in order to minimise losses. By reducing the distance covered by the milk, the device is also reduced in size and complexity of small intermediate portions. In particular, the breast shield nipple tunnel **9** may extend less than 70 mm from its start to end, more preferably less than 50 mm. In use, the nipple tunnel **9** is substantially aligned with the user's nipple and areolae. The nipple tunnel comprises a first opening **9**A for depositing milk into the collection container and a second opening **19**A for transferring negative air pressure generated by the pump to the user's nipple.

The shield flange **7**A and nipple tunnel **9** may be detachable from the housing **1** together. The shield flange **7**A and nipple tunnel **9** being detachable together helps further simplify the design, and reduce the number of components which must be removed for cleaning and sterilization. However, preferably, the nipple tunnel **9** will be integral with the breast shield **7**, in order to simplify the design and reduce the number of components which must be removed for cleaning and sterilisation.

FIGS. **3** and **4** are of a partially disassembled breast pump **100** of the present invention. In these Figures, the breast shield **7** has been disengaged from the housing **1** and milk collection bottle **3**. As shown in FIG. **4**, the housing **1** comprises a region or slot **11** for receiving the breast shield nipple tunnel **9** of the breast shield **7**. The breast shield is held in place thanks to a pair of channels (**9**B) included in the nipple tunnel **9**, each channel including a small indent. When pushing the housing **1** onto the breast shield **7**, which has been placed over the breast, ridges in the housing (**9**C) engage with the channels, guiding the housing into position; a small, spring plunger, such as ball bearing in each ridge facilitates movement of the housing on to the nipple tunnel **9**. The ball bearings locate into the indent to secure the housing on to the nipple tunnel with a light clicking sound. In this way, the user can with one hand place and position the breast shield **7** onto her breast and with her other hand, position and secure the housing **1** on to the breast shield **7**. The breast shield **7** can be readily separated from the housing **1** since the ball bearing latch only lightly secures the breast shield **7** to the housing **1**.

Alternatively, the breast shield **7** may also be held in place by means of a clip engaging with a slot located on the housing. The clip may be placed at any suitable point on the shield **7**, with the slot in a corresponding location.

The breast shield nipple tunnel **9** of the breast shield **7** is provided with an opening **9**A on its lower surface through which expressed milk flows. This opening **9**A is configured to engage with the milk collection bottle **3**.

The breast pump **100** further comprises a barrier or diaphragm for transferring the pressure from the pump to the milk-collection side of the system. In the depicted example, this includes flexible rubber diaphragm **13** seated into diaphragm housing **19**A. The barrier could be any other suitable component such as a filter or an air transmissive material. Diaphragm housing **19**A includes a small air hole into the nipple tunnel **9** to transfer negative air pressure into nipple tunnel **9** and hence to impose a sucking action on the nipple placed in the nipple tunnel **9**.

Hence, the air pump acts on one side of the barrier or diaphragm **13** to generate a negative air pressure on the opposite, milk-flow side of the barrier. The barrier has an outer periphery or surface, i.e. the surface of diaphragm housing **19**A that faces towards the breast, and the milk-flow pathway extends underneath the outer periphery or surface of the barrier or diaphragm housing **19**A. The milk-flow path extending under the outer periphery or surface of the barrier **19**A allows for a simpler and more robust design, without the milk-flow pathway extending through the barrier. This provides increased interior space and functionality for the device.

As noted, the milk-flow pathway extends beneath or under the barrier **13** or surface of diaphragm housing **19**A. This provides an added benefit of having gravity move the milk down and away from the barrier.

Preferably the milk-flow pathway does not pass through the barrier **32**. This results in a simpler and smaller barrier design.

As noted, the diaphragm **13** is mounted on diaphragm housing **19**A that is integral to the breast shield. This further helps increase the ease of cleaning and sterilisation as all of the components on the "milk" flow side can be removed.

The barrier **13** may also provide a seal to isolate the air pump from the milk-flow side of the barrier. This helps to avoid the milk becoming contaminated from the airflow or pumping side (i.e. the non-milk-flow side).

Alternatively, the only seal is around an outer edge of the barrier **13**. This is a simple design as only a single seal needs to be formed and maintained. Having multiple seals, such as for an annular membrane, introduces additional complexity and potential failure points.

As illustrated in FIGS. **3** and **4**, the barrier may include a flexible diaphragm **13** formed by a continuous circular disc shaped membrane which is devoid of any openings or holes. This provides a larger effective "working" area of the diaphragm (i.e. the area of the surface in contact with the pneumatic gasses) than an annular membrane and hence the membrane may be smaller in diameter to have the same working area.

The diaphragm **13** is arranged so that the milk-flow pathway extends below and past the outer surface or periphery of the diaphragm **13**. This means that the milk-flow pathway does not extend through the diaphragm **13**. In particular, the milk-flow pathway is beneath the diaphragm **13**. However, the diaphragm **13** may be offset in any direction with respect to the milk-flow pathway, provided that the milk-flow pathway does not extend through the diaphragm **13**.

Preferably, the diaphragm **13** is a continuous membrane, devoid of any openings. The diaphragm **13** is held in a diaphragm housing **19**, which is formed in two parts. The first half **19**A of the diaphragm housing **19** is provided on the outer surface of the breast shield **7**, above the breast shield nipple tunnel **9** and hence the milk-flow pathway. In preferred embodiments, the first half **19**A of the diaphragm housing **19** is integral with the breast shield. The second half **19**B of the diaphragm housing is provided in a recessed portion of the housing **1**. The diaphragm **13** self-seals in this diaphragm housing **19** around its outer edge, to form a watertight and airtight seal. Preferably, the self-seal around the outer edge of the diaphragm **13** is the only seal of the diaphragm **13**. This is beneficial over systems with annular diaphragms which must seal at an inner edge as well. Having the diaphragm **13** mounted in the breast pump **100** in this manner ensures that it is easily accessible for cleaning and replacement. It also ensures that the breast shield **7** and diaphragm **13** are the only components which need to be removed from the pump **100** for cleaning. Because the diaphragm **13** self-seals under vacuum pressure, it is easily removed for cleaning when the device is turned off.

FIGS. **5** and **6** show a breast pump **100** according to the present invention in a further disassembled state. In addition to the breast shield **7** and diaphragm **13** being removed, the milk collection container **3** has been unclipped. Preferably, the milk collection container **3** is a substantially rigid component. This ensures that expressed milk does not get wasted, while also enhancing re-usability. In some embodiments, the milk collection container **3** may be formed of three sections: a front bottle potion, a rear bottle portion, and a cap. These three sections may clip together to form the milk collection container **3**. This three-part system is easy to empty, easily cleanable since it can be dis-assembled, and easily re-usable. The milk collection container or milk bottle may be formed of at least two rigid sections which are connectable. This allows simple cleaning of the container for re-use. Alternatively, the container may be a single container made using a blow moulding construction, with a large opening to facilitate cleaning. This large opening is then closed with a cap with an integral spout **35** or 'sealing plate' (which is bayonet-mounted and hence more easily cleaned than a threaded mount spout). A flexible rubber valve **37** (or 'sealing plate seal') is mounted onto the cap or spout **35** and includes a rubber duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump; this ensures that negative air-pressure does not need to be applied to the milk container and hence adds to the efficiency of the system. The flexible valve **37** self-seals against opening **9**A in nipple tunnel **9**. Because it self-seals under vacuum pressure, it automatically releases when the system is off, making it easy to remove the milk container.

Preferably, the milk collection container resides entirely below the milk flow path defined by the breast shield when the breast pump system **100** is positioned for normal use, hence ensuring fast and reliable milk collection.

The milk collection container **3** has a capacity of approximately 5 fluid ounces (148 ml). Preferably, the milk collection container has a volume of greater than 120 ml. More preferably, the milk collection container has a volume of greater than 140 ml. To achieve this, the milk collection container **3** preferably has a depth in a direction extending away from the breast in use, of between 50 to 80 mm, more preferably between 60 mm to 70 mm, and most preferably between 65 mm to 68 mm.

The milk collection container **3** further preferably has a height, extending in the direction from the bottom of the container **3** in use to the cap or spout or sealing plate **35**, of between 40 mm to 60 mm, more preferably between 45 mm to 55 mm, and most preferably between 48 mm to 52 mm. The cap **35** may screw into the milk collection bottle **3**. In particular, it may be provided with a threaded connection or a bayonet and slot arrangement.

Further preferably, the milk collection container has a length, extending from the leftmost point to the rightmost point of the container **3** in use, of between 100 mm to 120 30 mm, more preferably between 105 mm to 115 mm, and most preferably between 107 mm to 110 mm.

This cap **35** is provided with a one-way valve **37**, through which milk can flow only into the bottle. This valve **37** prevents milk from spilling from the bottle once it has been collected. In addition, the valve **37** automatically seals completely unless engaged to the breast shield **7**. This ensures that when the pump **100** is dismantled immediately after pumping, no milk is lost from the collection bottle **3**. It can be appreciated that this one-way valve **37** might also be placed on the breast shield **7** rather than in this bottle cap **35**.

Alternatively, the milk bottle **3** may form a single integral part with a cap **35**. Cap **35** may include an integral milk pouring spout.

In certain embodiments, a teat may be provided to attach to the annular protrusion **31**A or attach to the spout that is integral with cap **35**, to allow the container **3** to be used directly as a bottle. This allows the milk container to be used directly as a drinking vessel for a child. The milk collection container may also be shaped with broad shoulders such that it can be adapted as a drinking bottle that a baby can easily hold.

Alternatively, or in addition, a spout may be provided to attach to the protrusion **31**A for ease of pouring. A cap may also be provided to attach to the protrusion **31**A in order to seal the milk collection bottle **3** for easy storage.

The pouring spout, drinking spout, teat or cap may also be integral to the milk collection container.

Further, the removable milk collection container or bottle includes a clear or transparent wall or section to show the amount of milk collected. Additionally, measurement mark-

ings (**3**A) may also be present on the surface of the container. This allows the level of milk within the container to be easily observed, even while pumping. The milk collection container or bottle may for example be made using an optically clear, dishwasher safe polycarbonate material such as Tritan™.

The milk collection container or bottle may include a memory or a removable tag, such as a tag including an NFC chip, that is programmed to store the date and time it was filled with milk, using data from the breast pump system or a connected device such as a smartphone. The container therefore includes wireless connectivity and connects to a companion app. The companion app then tracks the status of multiple milk collection containers or bottles to select an appropriate container or bottle for feeding. The tag of the bottle may also be programmed to store the expiry date of the milk as well as the quantity of the milk stored.

FIGS. **7** and **8** show front views of a breast pump system **100**. The outer-surface of the housing **1** has been drawn translucent to show the components inside. The control circuitry **71** for the breast pump **100** is shown in these figures. The control circuitry in the present embodiment comprises four separate printed circuit boards, but it is appreciated that any other suitable arrangement may be used.

The control circuitry may include sensing apparatus for determining the level of milk in the container **3**. The control circuitry may further comprise a wireless transmission device for communicating over a wireless protocol (such as Bluetooth) with an external device. This may be the user's phone, and information about the pumping may be sent to this device. In embodiments where the user interface comprises a breast toggle button **5**E, information on which breast has been selected by the user may also be transmitted with the pumping information. This allows the external device to separately track and record pumping and milk expression data for the left and right breasts.

There should also be a power charging means within the control circuitry **71** for charging the battery **81**. While an external socket, cable or contact point may be required for charging, a form of wireless charging may instead be used such as inductive or resonance charging. In the Figures, charging port **6** is shown for charging the battery **81**. This port **6** may be located anywhere appropriate on the housing **1**.

FIG. **8** shows the location of the battery **81** and the pumps **83**A, **83**B mounted in series inside the housing **1**. While the depicted embodiment shows two pumps **83**A, **83**B it is appreciated that the present invention may have a single pump. Preferably, an air filter **86** is provided at the output to the pumps **83**A, **83**B. In preferable embodiments, the pumps **83**A, **83**B are piezoelectric air pumps (or piezo pumps), which operate nearly silently and with minimal vibrations. A suitable piezo pump is manufactured by TTP Ventus, which can deliver in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free flow. The rear side of the second half of the diaphragm housing **19**B in the housing **1** is provided with a pneumatic connection spout. The pumps **83**A, **83**B are pneumatically connected with this connection spout.

Operation of the breast pump **100** will now be described. Once the breast pump **100** is activated and a pumping cycle is begun, the pumps **83**A, **83**B generates a negative air pressure which is transmitted via an air channel to a first side of the diaphragm **13** mounted on the diaphragm housing **19**A. This side of the diaphragm **13** is denoted the pumping side **13**B of the diaphragm **13**.

The diaphragm **13** transmits this negative air pressure to its opposite side (denoted the milk-flow side **13**A). This negative pressure is transferred through a small opening in the diaphragm housing **19**A to the breast shield nipple tunnel **9** and the curved opening **7**B of the breast shield **7** that contacts the breast. This acts to apply the pressure cycle to the breast of the user, in order to express milk. The milk is then drawn through the nipple tunnel **9**, to the one way valve **37** that remains closed whilst negative pressure is applied. When the negative air pressure is released, the valve **37** opens and milk flows under gravity past the valve **37** and into milk container **3**. Negative air pressure is periodically (e.g. cyclically, every few seconds) applied to deliver pre-set pressure profiles such as profiles that imitate the sucking of a child.

While the depicted embodiment of the breast pump **100** is provided with two pumps, the following schematics will be described with a single pump **83**. It is understood that the single pump **83** could be replaced by two separate piezo air-pumps **83**A, **83**B as above.

FIG. **9** depicts a schematic of a further embodiment of a breast shield nipple tunnel **9** for a breast pump **100**. The breast shield nipple tunnel **9** is provided with an antechamber **91** and a separation chamber **93**. A protrusion **95** extends from the walls of the breast shield nipple tunnel **9** to provide a tortuous air-liquid labyrinth path through the breast shield nipple tunnel **9**. In the separation chamber **93** there are two opening **97**, **99**. An air opening **97** is provided in an upper surface **93**A of the separation chamber **93**. This upper surface **93** is provided transverse to the direction of the breast shield nipple tunnel **9**. This opening **97** connects to the first side of the diaphragm housing **19**A and is the source of the negative pressure. This airflow opening **97** also provides a route for air to flow as shown with arrow **96**. It is appreciated that the tortuous pathway is not necessary and that a breast shield nipple tunnel **9** without such a pathway will work.

The other opening **99** is a milk opening **99**. The milk opening **99** is provided on a lower surface **93**B of the separation chamber **93** and connects in use to the container **3**. After flowing through the tortuous breast shield nipple tunnel **9** pathway, the milk is encouraged to flow through this opening **99** into the container **3**. This is further aided by the transverse nature of the upper surface **93**A. In this manner, expressed milk is kept away from the diaphragm **13**. As such, the breast pump **100** can be separated into a "air" side comprising the pump **83**, the connection spout **85** and the pumping side **13**B of the diaphragm **13** and a "milk-flow" side comprising the breast shield **7**, the milk collection container **3** and the milk-flow side **13**A of the diaphragm **13**. This ensures that all of the "milk-flow" components are easily detachable for cleaning, maintenance and replacement. Additionally, the milk is kept clean by ensuring it does not contact the mechanical components. While the present embodiment discusses the generation of negative pressure with the pump **83**, it will be appreciated that positive pressure may instead be generated.

While the embodiments described herein use a diaphragm **13**, any suitable structure to transmit air pressure while isolating either side of the system may be used.

The breast pump may further comprise a pressure sensor in pneumatic connection with the piezo pump. This allows the output of the pump to be determined.

FIG. **10** shows a schematic of a basic pneumatic system **200** for a breast pump **100**. In the system **200** milk expressed into the breast shield **7** is directed through the breast shield nipple tunnel **9** through the torturous air-liquid labyrinth

interface **95**. The milk is directed through the non-return valve **37** to the collection container **3**. This side of the system forms the "milk-flow" side **201**.

The rest of the pneumatic system **200** forms the air side **202** and is separated from contact with milk. This is achieved by way of a flexible diaphragm **13** which forms a seal between the two sides of the system. The diaphragm **13** has a milk-flow side **13**A and an air side or pumping side **13**B.

The air side **202** of the system **200** is a closed system. This air side **202** may contain a pressure sensor **101** in pneumatic connection with the diaphragm **13** and the pump **83**. Preferably, the pump **83** is a piezoelectric pump (or piezo pump). Due to their low noise, strength and compact size, piezoelectric pumps are ideally suited to the embodiment of a small, wearable breast pump. The pump **83** has an output **83**A for generating pressure, and an exhaust to the atmosphere **83**B. In a first phase of the expression cycle, the pump **83** gradually applies negative pressure to half of the closed system **202** behind the diaphragm **13**. This causes the diaphragm **13** to extend away from the breast, and thus the diaphragm **13** conveys a decrease in pressure into the breast shield **7**. The reduced pressure encourages milk expression from the breast, which is directed through the tortuous labyrinth system **95** and the one-way valve **37** to the collection bottle **3**.

While in the depicted embodiment the air exhaust **83**B is not used, it may be used for functions including, but not limited to, cooling of electrical components, inflation of the bottle to determine milk volume (discussed further later) or inflation of a massage bladder or liner against the breast. This massage bladder may be used to help mechanically encourage milk expression. More than one massage bladder may be inflated regularly or sequentially to massage one or more parts of the breast. Alternatively, the air pump may be used to provide warm air to one or more chambers configured to apply warmth to one or more parts of the breast to encourage let-down.

The air side **202** further comprises a two-way solenoid valve **103** connected to a filtered air inlet **105** and the pump **83**. Alternatively, the filter could be fitted on the pump line **83**A. If the filter is fitted here, all intake air is filtered but the performance of the pump may drop. After the negative pressure has been applied to the user's breast, air is bled into the system **202** through the valve **103** in a second phase of the expression cycle. In this embodiment, the air filter **105** is affixed to this inlet to protect the delicate components from degradation. In particular, in embodiments with piezoelectric components, these are particularly sensitive.

The second phase of the expression cycle and associated switching of valve **103** is actioned once a predefined pressure threshold has been reached. The pressure is detected by a pressure sensor **101**.

In certain embodiments, if the elasticity and extension of the diaphragm **13** may be approximated mathematically at different pressures, the pressure measured by sensor **101** can be used to infer the pressures exposed to the nipple on the opposite side of the diaphragm **13**. FIG. **11** shows an alternative pneumatic system **300**. The core architecture of this system is the same as the system shown in FIG. **10**.

In this system **300**, the closed loop **202** is restricted with an additional three way solenoid valve **111**. This valve **111** allows the diaphragm **13** to be selectively isolated from the rest of the closed loop **202**. This additional three way valve **111** is located between the diaphragm **13** and the pump **83**. The pressure sensor **101** is on the pump **83** side of the three way valve **111**. The three way valve **111** is a single pole double throw (SPDT) valve, wherein: the pole **111**A is in pneumatic connection with the pump **83** and pressure sensor; one of the throws **11** is in pneumatic connection with the diaphragm **13**; and the other throw **111**C is in pneumatic connection with a dead-end **113**. This dead-end **113** may either be a simple closed pipe, or any component(s) that does not allow the flow of air into the system **202**. This could include, for example, an arrangement of one-way valves.

In this system **300**, therefore, the pump **83** has the option of applying negative pressure directly to the pressure sensor **101**. This allows repeated testing of the pump in order to calibrate pump systems, or to diagnose issues with the pump in what is called a dead end stop test. This is achieved by throwing the valve to connect the pump **83** to the dead end **113**. The pump **83** then pulls directly against the dead end **113** and the reduction of pressure within the system can be detected by the pressure sensor **101**.

The pressure sensor detects when pressure is delivered and is then able to measure the output of the pumping mechanism. The results of the pressure sensor are then sent to an external database for analysis such as a cloud database, or are fed back to an on-board microcontroller that is located inside the housing of the breast pump system.

Based on the pressure sensor measurements, the breast pump system is able to dynamically tune the operation of the pumping mechanism (i.e. the duty or pump cycle, duration of a pumping session, the voltage applied to the pumping mechanism, the peak negative air pressure) in order to ensure a consistent pressure performance across different breast pump systems.

In addition, the breast pump system, using the pressure sensor measurements, is able to determine if the pump is working correctly, within tolerance levels. Material fatigue of the pump is therefore directly assessed by the breast pump system. Hence, if the output of the pumping mechanism degrades over time, the breast pump system can tune the pumping mechanism operation accordingly. As an example, the breast pump system may increase the duration of a pumping session or the voltage applied to the pumping mechanism to ensure the expected pressures are met.

This ensures that the user experience is not altered, despite the changing output of the pump as it degrades over time. This is particularly relevant for piezo pumps where the output of the pump may vary significantly.

The microcontroller can also be programmed to deliver pre-set pressure profiles. The pressure profiles may correspond to, but not necessarily, any suction patterns that would mimic the sucking pattern of an infant. The patterns could mimic for example the sucking pattern of a breastfed infant during a post birth period or at a later period in lactation.

The profiles can also be manually adjusted by the user using a control interface on the housing of the breast pump system or on an application running on a connected device.

Additionally, the user is able to manually indicate the level of comfort that they are experiencing when they are using the system. This can be done using a touch or voice-based interface on the housing of the breast pump system itself or on an application running on a connected device.

The system stores the user-indicated comfort levels together with associated parameters of the pumping system. The pressure profiles may then be fine scaled in order to provide the optimum comfort level for a particular user.

The profiles or any of the pumping parameters may be calculated in order to correlate with maximum milk expression rate or quantity.

The pressure profiles or any of the pumping parameters may also be dynamically adjusted depending on the real time milk expression rate or quantity of milk collected. The pressure profiles or any of the pumping parameters may also be dynamically adjusted when the start of milk let-down has been detected.

Additionally, the system is also able to learn which parameters improve the breast pump system efficiency. The system is able to calculate or identify the parameters of the pumping mechanism that correlate with the quickest start of milk let-down or the highest volume of milk collected for a certain time period. The optimum comfort level for a particular user may also be taken into account.

FIG. **12** shows a schematic for a system **400** for a breast pump **100** which can estimate the volume of milk collected in the collection container **3** from data collected on the air-side part **202** of the system **400**.

The pump **83** is connected to the circuit via two bleed valves **126**, **128**. The first bleed valve **126** is arranged to function when the pump **83** applies a negative pressure. As such, this valve **126** is connected to a "bleed in" **127**, for supplying atmospheric air to the system **202**.

The second bleed valve **128** is arranged to function when the pump **83** applies a positive pressure. As such, this valve **128** is connected to a "bleed out" **129** for bleeding air in the system **202** to the atmosphere.

Although Section C describes the preferred embodiment for measuring or inferring the volume of milk collected in the milk collection container using IR sensors, an alternative method for measuring or inferring the volume of milk collected in the milk collection container using pressure sensors is described also below.

During a milking pump cycle, the pump **83** applies negative pressure on the air side **13**B of the diaphragm **13** which causes its extension towards the pump **83**. This increases the volume of the space on the milk side **13**B of the diaphragm **13**. This conveys the decrease in pressure to the breast to encourage expression of milk. A set of three non-return valves **121**, **123**, **125** ensure that this decrease in pressure is applied only to the breast (via the breast shield **7**) and not the milk collection container **3**. To measure the volume of milk collected in the container **3**, the pump **83** is used instead to apply positive pressure to the diaphragm **13**. The diaphragm **13** is forced to extend away from the pump **83** and conveys the pressure increase to the milk side **201** of the system **400**. The three non-return valves **121**, **123**, **125** ensure that this increase in pressure is exclusively conveyed to the milk collection container **13**.

The breast pump may further comprise: a first non-return valve between the milk flow side of the diaphragm and the breast shield, configured to allow only a negative pressure to be applied to the breast shield by the pump; a second non-return valve between the milk-flow side of the diaphragm and the milk collection container configured to allow only a positive pressure to be applied to the milk collection container by the pump; and a pressure sensor in pneumatic connection with the pressure-generation side of the diaphragm.

The resulting pressure increase is monitored behind the diaphragm **13** from the air-side **202** by a pressure sensor **101**. Preferably, the pressure sensor **101** is a piezoelectric pressure sensor (piezo pressure sensor). The rate at which the pump **83** (at constant strength) is able to increase the pressure in the system **400** is a function of the volume of air that remains in the milk collection container **3**. As air is many times more compressible than liquid, the rate at which pressure increases in the system **400** can be expressed as an approximate function of the volume of milk held in the collection container **3**.

Thus by increasing the pressure in this fashion, the rate of pressure increase can be determined, from which the volume of milk held in the container **3** is calculable. FIG. **13** shows repeated milking and volume measurement cycles as the collection container **3** is filled. To determine the rate of pressure increase the pump **83** was run for a fixed time. As pumping proceeds and the volume of air reduces in the system **400**, the pump **83** is able to achieve a higher pressure. Each milking cycle is represented by a positive pressure spike **41**. There is a clear upwards trend **43** in magnitude of positive pressures achieved as the collection container **3** is filled.

A method of estimating the pressure applied by a breast pump may comprise the steps of: selecting a pressure cycle from a pre-defined list of pressure cycles; applying pressure with the pump to stimulate milk expression; reading the output of the pressure sensor; and adjusting the applied pressure of the pump to match the pressure profile selected. This allows for repeatable application of force to the breast, even as the pump performance degrades.

Preferably the method further comprises the steps of: approximating the elasticity and extension of the diaphragm at the relevant pressure; and calculating an estimated applied pressure based upon the output of the pressure sensor and the approximated elasticity and extension of the diaphragm.

Alternatively, a method of estimating the milk collected by a breast pump may comprise the steps of: generating a positive pressure with the pump; transmitting the positive pressure via the diaphragm and second non-return valve to only the milk collection container; measuring the increase in pressure by the pressure sensor in pneumatic connection with the diaphragm; estimating the volume of milk inside the milk collection container based upon the rate of increase of pressure. In this manner, the volume of milk can be estimated remotely.

In this manner, an estimate can be obtained for the volume of milk in the container **3** based upon the measured pressures.

FIG. **13** also shows a dead end stop pump test **45** as described above. The negative spike shows the application of negative pressure directly to the pressure sensor **101**.

2. Breast Shield Sizing and Nipple Alignment

The correct sizing of the breast shield and the alignment of the nipple in the breast shield are key for an efficient and comfortable use of the breast pump. However breast shape, size as well as nipple size and position on the breast vary from one person to another and one breast from another. In addition, women's bodies often change during the pumping life cycle and consequently breast shield sizing may also need to be changed. Therefore, a number of breast shield sizes are available. Guide lines for correct nipple alignment are also provided.

With reference to FIG. **14**, three breast shield sizes are shown (A1, B1, C1). The substantially clear breast shield gives an unobstructed view of the breast and allows a user to easily confirm that she has the appropriate sized shield for her breast.

In order to determine the correct breast shield size and nipple alignment, the breast shield and the diaphragm are detached from the housing and placed on the breast with the sizing symbol facing upwards (with the diaphragm positioned below the nipple) and the nipple aligned in the centre of the fit lines (as shown in A2, B2, C2). The transparent breast shield allows the user to observe the nipple while

adjusting the position of the breast shield in order to align the nipple correctly near the centre of the breast shield nipple tunnel. Prior to using the pump, the nipple is aligned correctly, and the breast shield is pushed into place ensuring the seal is correctly positioned on the breast shield. The fit lines should be directly aligned with the outside of the nipple. The correct alignment is illustrated B2.

When the nipple is correctly aligned, the user then rotates the breast shield in order for the diaphragm to be positioned on top of the nipple. The user may then quickly assemble the rest of the breast pump (i.e. the housing and the milk container) on the breast shield via a one-click attachment mechanism confirming correct engagement, which may be performed one-handed. Nipple alignment may therefore be easily maintained. Audio and/or haptic feedback may also be provided to further confirm correct engagement.

3. Connected Device Application

FIGS. **15** to **20** show examples of screenshots of a connected device application that may be used in conjunction with the breast pump system as described above. The interface shown here is an example only and the same data may be presented via any conceivable means including animated graphics, device notifications, audio or text descriptions.

FIG. **15** shows a homepage of the application with different functions provided to the user which can be accessed either directly while pumping or at a later time in order for example: to review pump settings or the history of previous pumping sessions.

FIG. **16** shows a status page with details of remaining battery life, pumping time elapsed and volume of milk inside the milk container.

FIG. **17** shows screenshots of a control page, in which a user is able to control different pump parameters for a single breast pump (A) or two breast pumps (B). The user may press on the play button to either start, pause, or resume a pumping activity. The user may also directly increase or decrease the rate of expression using the (+) or (−) buttons. When only one breast is being pumped (A), the user may also indicate if it is either the right or left breast that is being pumped. The user may also control the pump peak pressure or alternatively may switch between different pre-programmed pressure profiles such as one mimicking the sucking pattern of a baby during expression or stimulation cycle.

FIG. **18** shows a page providing a summary of the last recorded pumping session.

FIG. **19** shows a page providing a history of previous pumping sessions. The user may scroll down through the page and visualize the data related to specific pumping sessions as a function of time.

The application is also capable of providing notifications relating to pumping. FIG. **20** shows a screenshot of the application, in which a user is provided a notification when the milk collection bottle is full. Other generated notifications may include warnings about battery life, Bluetooth connection status or any other wireless communication status, status of miss-assembly, excessive movement or lack of expression.

FIG. **21** shows a further example with a screenshot of an application running on a connected device. The page shows the pumping status when a user is using a double pump mode of operation with a pump on each breast. The user is able to manually control each pump individually and may start, stop or change a pumping cycle, increase or decrease each pump peak pressure, or switch between different pre-program pressure profiles such as one mimicking the sucking pattern of a baby during an expression or stimulation cycle. The application also notifies the user when a milk collection container is nearly full as shown in FIG. **22**.

FIG. **23** shows a status page with an alert notifying the user that the milk collection container of the pump on the right breast is full. A message is displayed that the pump session has paused and that the milk collection container should be changed or emptied before resuming pumping.

With reference to FIG. **24**, when the left and right pump are stopped or paused, the application displays the elapsed time since the start of each session (right and left), the total volume of milk collected in each bottle.

With reference to FIG. **25**, a page summarising the last session (with a double pump mode) is displayed.

In addition to the data provided to the user, and their interactions with the application, the app will also hold data that the user does not interact with. For example, this may include data associated with pump diagnostics. In addition to all functions and sources of data discussed above, the application may itself generate metadata associated with its use or inputs, notes or files uploaded by the user. All data handled within the mobile application can be periodically transferred to a cloud database for analysis. An alternative embodiment of the breast pump system may include direct contact between the database and the pump, so that pumping data may be conveyed directly, without the use of a smartphone application.

In addition to providing data to the cloud, the application may also provide a platform to receive data including for example firmware updates.

4. Breast Pump Data Analysis

The discreet, wearable and fully integrated breast pump may offer live expression monitoring and intelligent feedback to the user in order to provide recommendations for improving pump efficiency or performance, user comfort or other pumping/sensing variables, and to enable the user to understand what variables correlate to good milk flow.

Examples of variables automatically collected by the device are: time of day, pump speed, pressure level setting, measured pressure, pressure cycle or duty cycle, voltage supplied to pumps, flow rate, volume of milk, tilt, temperature, events such as when let-down happens, when a session is finished. The user can also input the following variables: what side they have pump with (left or right or both), and the comfort level.

This is in part possible because the live milk volume measurement system functions reliably (as discussed in Section B). The breast pump system includes a measurement sub system including IR sensors that measures or infers milk flow into the milk container, and that enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. The generated data may then be distributed to a connected device and/or to a cloud server for analysis in order to provide several useful functions.

FIG. **26** illustrates an outline of a smart breast pump system network which includes the breast pump system (**100**) in communication with a peripheral mobile device and application (**270**) and several cloud-based databases (**268**, **273**). The breast pump system (**100**) includes several sensors (**262**). Sensor data refers to a broad definition including data generated from any sensor or any other analogue/digital reading directly from the motherboard or any other component. However, within the embodiment detailed, these measurements include one or more of the following, but not limited to: milk volume measurements, temperature sensor readings, skin temperature sensing, pressure sensor readings, accelerometer data and user inputs through any physical device interface.

The device also contains a number of actuators, including, but not restricted to: piezoelectric pump(s), solenoid valve (s), IREDs and an LED display. Sensors and actuators within the device are coordinated by the CPU (**263**). In addition, any interactions, and data from these components, may be stored in memory (**264**).

Further to these components, the device also contains a communication chip, such as a Bluetooth chip (**265**) which can be used to communicate wirelessly with connected devices such as a peripheral mobile device (**270**). Through this connection any sensor data (**267**) generated in the breast pump can be sent to the connected device. This user data, along with any other metadata generated from a connected device app, can be provided to an online database which aggregates all user data (**273**). In addition, the communication chip will also allow the sending of user control data/ firmware updates from the connected device to the breast pump system (**266**).

Raw data (**271**) collected from the measurement sub-system including sensors (**262**) may be analysed on a cloud database and the analysed data may be stored on the cloud (**272**). Through inferences provided by the analysed data, firmware updates (**269**) may be developed. These can be provided for download to the pump through, for example, an online firmware repository or bundled with the companion app in the connected device app store (**268**).

In addition, it should be appreciated that despite the sophistication of the proposed breast pump network, the breast pump still retains complete functionality without wireless integration into this network. Relevant data may be stored in the device's memory (**264**) which may then be later uploaded to the peripheral portion of the system when a connection is established, the connection could be via USB cable or wireless.

The measurement sub-system may analyse one or more of the following:

- the quantity of the liquid in the container above its base;
- the height of the liquid in the container above its base;
- the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase, a haptic and/or visual indicator indicates if the pump is operating correctly to pump milk. For example, the visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The visual indicator may provide:

- an estimation of the flow rate;
- an estimation of the fill rate;
- an indication of how much of the container has been filled.

As a further example, an accelerometer may infer the amount of movement or tilt angle during a pumping session. If the tilt angle excesses a threshold, the system warns or alerts the user of an imminent spillage, or provides the user with an alert to change position. Alternatively, the system may also stop pumping to prevent spillage, and once the tilt angle reduces below the threshold, pumping may resume automatically. By sensing the movement or title angle during a pumping session, the system may also derive the user's activity such as walking, standing or lying.

Many variables can affect milk expression and data analysis of these multiple variables can help mothers to achieve efficient pumping regimes and improve the overall user experience.

Therefore, the measurement sub-system measures or infers milk flow into the milk container and enables a user to understand what variables (e.g. time of day, pump setting) correlates to good milk flow. The amount of milk expressed over one or more sessions is recorded as well as additional metrics such as: time of day, pump setting, length of a single pumping session, vacuum level, cycle times, comfort, liquids consumed by the mother. Live data or feedback is then provided to the user to ensure the breast pump is being used properly and to support the user in understanding the variables that would correspond to the specific individual optimum use of the breast pump.

Furthermore, live data can be used to automatically and intelligently affect specific pumping parameters in order to produce the most efficient pumping session. For example, if the rate of expression increases, the milking cycle might be adjusted accordingly to achieve a more efficient, or more comfortable pumping cycle.

The measurement sub-system also enables a data analysis system to determine patterns of usage in order to optimally control pumping parameters. Collected metrics are transferred through wireless connections between the pump, a connected device or app and a cloud database. Additionally, the application can also connect to other apps residing on the connected device, such as fitness app or social media app or any other apps. Further metrics may also include the behaviour or specific usage of the user associated with the connected device while using the pump (detection of vision and/or audio cues, internet usage, application usage, calls, text message).

Different aspects of pumping can be automatically changed based on dynamic sensor feedback within the breast pump device. The data analysis system is able to access real-time data of pumping sessions and may be used to perform one or more of the following functions, but not limited to:

- indicate whether the milk is flowing or not flowing,
- measure or infer the quantity and/or height of the liquid in the container above its base,
- give recommendations to the mother for optimal metrics for optimal milk flow,
- give recommendations to the mother for optimal metrics for weaning,
- give recommendations to the mother for optimal metrics for increasing milk supply (e.g. power pumping),
- give recommendations to the mother for optimal metrics if an optimal session start time or a complete session has been missed,
- automatically set metrics for the pumping mechanism, such as length of a single pumping session, vacuum level, cycle times.
- automatically stop pumping when the milk container is full,
- automatically adjust one or more pumping parameters to achieve an optimum pumping session,
- automatically adjust one or more pumping parameters to achieve a comfortable pumping session,
- automatically change the pumping cycle from a programmed cycle to another different programmed cycle, such as from a stimulation cycle to an expression cycle.

In addition, sensor feedback might be used to improve the physical function of the breast pump system itself. For example, an array of piezoelectric pumps may be dynamically adjusted in response to their operating temperatures so as to optimise the total life of the component whist maintaining peak pressures.

Many additional embodiments may be described for these simple feedback systems, yet the premise remains: real-time sensor feedback is used to automatically and dynamically

adjust actuator function. Each feedback program may feasibly include any number and combination of data sources and affect any arrangement of actuators.

The data generated can also be used to generate large datasets of pumping parameters, user metadata and associated expression rates, therefore allowing the analysis of trends and the construction of associations or correlations that can be used to improve pumping efficiency, efficacy or any function related to effective milk expression. The analysis of large user datasets may yield useful general associations between pumping parameters and expression data, which may be used to construct additional feedback systems to include on firmware updates.

Multiple data sources can be interpreted simultaneously and several different changes to pumping might be actuated to increase pumping efficiency, user experience or optimize pump performance.

Collected metrics may be anonymised and exported for sharing to other apps, community or social media platforms on the connected device, or to an external products and services, such as community or social media platform. By contrasting the performance of different users in the context of associated metadata, users may be grouped into discrete 'Pumper profiles' or communities, which may then be used to recommend, or action the most appropriate selection of intelligent feedback systems to encourage efficient expression. For example, a higher peak pressure may be recommended for women who tend to move more whilst pumping, so as to achieve more efficient expression.

Section B: IR System

This section describes the milk detecting system used in the Elvie™ pump.

With reference to FIGS. **27** and **28**, there is shown a device **270** for use in detecting the level of liquid inside a container **275**. The device **270** is formed of a housing **271** in which is located a sensing assembly **272** comprising a series of optical emitters **273** (an array of three optical emitters is used on one implementation) which are relative to, and each located at a distance from, an optical receiver **274**. In operation of the device as will be described, each optical emitter **273** is operable to emit radiation which is received by the optical receiver **274**. In an embodiment of the invention, the series of optical emitters are each located equidistant from the optical receiver **274**.

The optical emitters **273** and the optical receiver **274** from the sensing assembly **272** are located in a portion **276** of the device **270** which faces the container **275** when the device is connected to the container **275**. The portion **276** of the device **270** containing the optical emitters **273** and the optical receiver **274** comprises a window **277** of material which is transparent to optical radiation. In this way, each of the optical emitters **273** and the optical receiver **274** have a line of sight through the window **277** into the container **275** when the device **270** is connected thereto.

A controller **278** comprising a CPU **279** and a memory **280** is provided in the device **270** for controlling the operation of the sensing assembly **272**. An accelerometer **281** is also provided in the housing **271**, which is operatively connected to the controller **278**. Operation of the device **270** when connected to the container **275** will now be described.

In a principal mode of operation, to determine the level L of liquid inside the container **275**, the controller **278** instructs the optical emitters **273** to each emit radiation towards the surface of the liquid inside the container **275** at a given intensity. The optical receiver **274** receives the reflected radiation from each optical emitter **273** via the surface of the liquid and each of these intensities is recorded by the controller.

For each operation of the sensing assembly **272**, the controller **278** records the intensities of radiation emitted by each of the optical emitters **273** as intensities IE**1**; IE**2** . . . IEn (where n is the total number of optical emitters), and records the intensities of radiation received by the optical receiver **274** from each of the optical emitters **273** as received intensities IR1; IR2 . . . IRn.

By comparing the emitted radiation intensities IE**1**; IE**2** . . . IEn with the received radiation intensities IR**1**; IR**2** . . . IRn, the controller **278** calculates a series of intensity ratios IE**1**:IR**1**; IE**2**:IR**2** . . . IEn:IRn, which are then used to determine the level of the liquid inside the container. At the most basic level, if the intensity ratio of IE**1**:IR**1** is the same as IE**2**:IR**2**, given the optical emitters **273** are equidistant from the optical receiver **274**, this indicates that the level of the liquid inside the container is parallel to the top of the bottle, as shown in FIG. **27**. In contrast, if these two intensity ratios are different, this indicates that the liquid level is at a different angle, such as that shown in FIG. **28**.

To accurately determine the level and the quantity of liquid inside the container **275**, the controller **278** processes the recorded intensity ratios using a database located in the memory **280**. The database contains an individual record for each container which is operable to connect with the device **270**. Each record from the database contains a look-up table of information, which contains expected intensity ratios (IE**1**:IR**1** and IE**2**:IR**2**) for the container **275** when filled at different orientations, and with different quantities of liquid.

By comparing the information from the look-up table with the recorded intensity ratios, the controller **278** calculates the level and quantity of liquid inside the container **275** and stores this information in the memory **280**.

In situations where a container **275** to the device **270** contains no stored record in the database, the sensing assembly **272** can be used in a calibration mode to create a new record. In the calibration mode, the sensing assembly **272** is operated as the container is filled from empty, and as it is positioned at different orientations. At each point during the calibration mode, the controller **278** calculates the recorded intensity ratios (IE**1**:IR**1** and IE**2**:IR**2**) and stores them in the record relating to the container **275**. For each set of recorded intensity ratios, the user includes information in the record relating to the orientation and fill level of liquid inside of the container **275**.

To improve the accuracy of the results obtained by the device **270** during its use, the controller **278** when recording each intensity ratio also records a parameter from the accelerometer **281** relating to the acceleration experienced by the device **270**. For each recorded acceleration parameter, the controller **278** determines whether the parameter **278** exceeds a predetermined threshold acceleration parameter stored in the memory **280**. The predetermined threshold is indicative of an excessive acceleration, which causes sloshing of liquid inside the container **275** connected to the device **270**. In the event of a recorded acceleration parameter exceeding the predetermined threshold acceleration parameter, the controller **278** flags the recorded intensity ratios associated with the recorded acceleration parameter as being unreliable (due to sloshing).

Even without the use of the accelerometer **281**, the controller **278** is nonetheless operable to determine whether a set of recorded intensity ratios occur during a period of excess acceleration. In this regard, for each set of intensity ratios recorded at a given time, the controller **278** checks

whether any of these intensity ratios is of a predetermined order of magnitude different than the remaining recorded intensity ratios from the set. In the event that the controller **278** determines that this is the case, this indicates that the liquid inside the container has 'sloshed' as a result of the excess acceleration, as shown in FIG. **29**. In this event, the controller **278** flags the set of recorded intensity ratios as being unreliable.

It will be appreciated that instead of recording the relative intensities of radiation emitted by the optical emitters **273** with the radiation received by the optical emitter **274**, the controller **278** could instead record the time taken for radiation emitted by each of the optical emitters **273** to be received by the optical receiver **274**. In this arrangement, the look up table would instead contain time periods as opposed to intensity ratios.

In terms of the applications for the device **270**, it will be appreciated that the device can be used in a wide variety of applications. One possible application is the use of the device **270** to determine the level of liquid located within a container **275**, such as a baby bottle, used as part of a breast pump assembly. In this arrangement, the device **270** is associated with a breast pump **301** which assists with the expression of milk from a breast. The breast pump may be located in the housing **271** of the device **270** as shown in FIG. **30**, or it may be realisably connected to the housing **271**.

Either way, the device **270** would be connectable to the container **275** such that milk expressed by the breast pump can pass from the pump via a channel **302** into the container **275**.

The breast pump may be any type of breast pump system including any shapes of milk container or bottle and may comprise a pump module for pumping milk from a breast. The pump module being contained within the housing may comprise: a coupling, a container attachable to the housing via the coupling to receive milk from the pump, a sensing assembly within the housing and comprising at least one optical emitter operable to emit optical radiation towards the surface of the body of milk held in the container when the housing is connected to the container, an optical receiver for receiving the reflected radiation from the surface of the milk, and a controller electrically connected to the sensing assembly for receiving signals from the optical receiver and calculating the level of the milk inside the container based on the reflected radiation received by the optical receiver.

By determining the level of milk inside the container based on reflected radiation from the surface of the milk in the container, there is no need to monitor the individual droplets of milk entering the container, such that the sensing assembly can avoid errors associated with measuring these droplets. For example, because we take multiple reflection-based measurements once the container is filled, we can generate an average measurement that that is more accurate than a single measurement. But with systems that rely in counting individual droplets, that is not possible—further, systemic errors (e.g. not counting droplets below a certain size) will accumulate over time and render the overall results unreliable. Furthermore, by not needing to measure these droplets, the sensing assembly from the breast pump need not always be on during the pumping process, which saves power.

When at least two optical emitters are used, the sensing assembly from the breast pump may determine the level of milk inside the container more accurately and irrespective of the orientation of the liquid level inside the container.

Each optical emitter may be equidistant from the optical receiver in order for the controller to easily calculate the level of the milk inside the container based on the reflected radiation originating from each optical emitter. The signals from the optical receiver preferably comprise information relating to the intensity of the radiation received by the optical receiver.

Each optical emitter may be operable to emit radiation at a different wavelength, or at a different time, than the other optical emitters. In this way, the controller can more easily process the signals from the optical receiver, and more easily distinguish between the radiation emitted by each of the optical emitters.

The optical emitter may emit radiation in the visible range of wavelengths. Alternatively, it may be UV or IR light. The emitted wavelength may be for example between 10 nm and 1 mm.

The sensing assembly may also comprise at least one accelerometer electrically connected to the controller. The controller may be configured to record an accelerometer parameter from the accelerometer and determine whether the accelerometer parameter exceeds a predetermined threshold. The predetermined threshold may be indicative of an excessive acceleration, which might cause sloshing of milk inside any container connected to the breast pump.

Another application for the device **270** is as a collar for detecting the level/quantity of liquid in a container **275**, such as a baby bottle, via its lid **310**. An example of the device **270** being used as such a collar is shown in FIG. **31**. In this arrangement, the device **270** is located between the container **275** and the lid **310**, and comprises a first end **311** having a first coupling **312** for attaching the collar to the lid **310**. The device comprises a second end **313** having a second coupling **314** for attaching the device **270** to the container **275**. The second coupling may be a screw thread, shown in FIG. **31**, on the inside surface of the container **275**. In this way, the distinctive bottom inside surface can be used by the sensing assembly **272** to more easily calibrate itself to the container **275** on which the distinctive bottom inside surface is located. The distinctive bottom may also be used to help identify which container **275** the device is connected to, and thus which record should be used from the database when the device **270** is used.

To further improve the accuracy of the sensing assembly **272**, the controller **278** may also be configured to use the recorded information from the accelerometer **281**, in situations where the record acceleration is below the predetermined threshold acceleration parameter, to calculate a more accurate liquid level and/or quantity of liquid located inside the container which is compensated for acceleration.

In one particular arrangement, the controller **278** may poll the accelerometer **281** prior to each operation of the sensing assembly **272** to verify that the device **270** is not currently undergoing excessive acceleration. In the event of the controller **278** determining excessive acceleration in the device **270**, the controller **278** would continually re-poll the accelerometer, and not operate the sensing assembly **272**, until the parameter from the accelerometer is determined as being below the predetermined threshold acceleration parameter stored in the memory **280**.

It will also be appreciated that for each container record stored in the database, the container record may comprise a plurality of look up tables, wherein each look up table is associated with a particular liquid used in the container, and wherein each look up table contains its own set of intensity

ratios. In this way, the device **270** can more accurately determine the level/quantity of different liquids used in a particular container **275**.

As described herein, the sensing assembly **272** has been described as having a plurality of optical emitters **273**. It will be appreciated however that the sensing assembly could operate using a single optical emitter **273** and plurality of optical receivers **274**. In this arrangement, each record from the database would contain a plurality of ratios relating to the emitted radiation from the optical emitter **273** as received by each of the optical receivers **274**. In use of the device **270**, the controller **278** would then similarly record the emitted radiation from the optical emitter **273** as received by each of the optical receivers **274**. In an alternate arrangement, there may be provided a plurality of optical emitters **273** and a plurality of optical receivers **274**, wherein each optical emitter **273** is associated with a respective optical receiver **274**. In its simplest arrangement, the sensing assembly **272** may comprise a single optical emitter **273** and a single optical receiver **274**.

In certain configurations, the optical emitters **273** may together emit radiation having the same wavelength. In other configurations, the optical emitters **273** may each emit radiation having a different wavelength. In this latter configuration, the optical receiver **274** would then be able to determine which optical emitter **273** is associated with any given received radiation, based on the wavelength of the received radiation.

The optical emitters **273** may also each emit radiation at different times, such to allow the controller **278** to more easily process the signals from the optical receiver **274**, and more easily distinguish between the radiation emitted by each of the optical emitters **273**.

In relation to the electrical connection between the controller **278** and the sensing assembly **272**, it will be appreciated this electrical connection may be either a wired/wireless connection as required.

Although not shown in the Figures, the device **270** herein described is preferably powered by a battery or some other power source located in the device **270**. In other embodiments, the device **270** may be powered using mains electricity.

In one configuration, it is also envisaged that rather than the controller **278** comparing the information from the look-up table with the recorded intensity ratios to calculate the level and quantity of liquid inside the container **275**, the controller **278** could instead process the recorded intensity ratios through a liquid-level equation stored in the memory **280**. In this configuration, the liquid-level equation could be a generalised equation covering a family of different containers, or could be an equation specific to a container having a given shape and/or type of liquid inside.

It will also be appreciated that in some applications of the device **270**, the device could be used to detect the level of a solid, as opposed to a liquid, in a container. As used herein, the terms 'optical emitter' and 'optical receiver' are intended to cover sensors which can emit radiation in or close to the optical wavelength. Any type of radiation at or close to the optical wavelength is suitable provided that it does not have any harmful effects. The exact wavelength is not important in the context of the invention. Such sensors thus include those which can emit visible radiation (such as radiation having wavelengths in the region of 400 nm-700 nm), and/or those which can emit IR radiation (such as radiation having wavelengths in the region of 700 nm-1 mm and/or those which can emit UV radiation (such as radiation having wavelengths in the region of 10 nm to 400 nm).

Existing prior art for such a sensor module is the apparatus disclosed in RU2441367. In this apparatus, the container is an industrially sized milk tank, which only includes a single laser mounted at the top of the tank. Whilst this apparatus is suited for large-sized containers, which do not move in use, the apparatus is less-suited for applications where the container moves in use, or where the liquid level inside the container is non perpendicular to the laser beam shone into the container. In contrast, the sensor module described above can be used in a variety of different applications, is conveniently located within a housing, and which by virtue of it having at least two optical emitters, can determine the level of liquid even inside containers of irregular shapes, and which can determine the level of liquid inside a container irrespective of the orientation of the liquid level inside the container.

Further to the embodiments of the fluid measurement system in different contexts, it can be appreciated that different functions entirely may be possible using the same component structure. For example, it is known that certain molecules within breast milk absorb specific wavelengths of light at characteristic propensities. Whilst the proposed system uses multiplexed IREDs at the same wavelengths to perform proximity measurements, the same array of IREDs may instead be used to emit several different wavelengths of light and determine their absorption upon reflection. If appropriately calibrated, the system may be able to report on the presence or concentration of specific compounds in the expressed milk, such as fat, lactose or protein content.

In addition to this embodiment, it is feasible that the system might be applied to monitor the change in volume of any other container of liquid, given there is sufficient reflection of IR off its surface. These embodiments might include for example: liquid vessel measurement such as for protein shakes, cement or paint, or volume measurements within a sealed beer keg.

Section C: Bra Clip

This section describes a bra clip that forms an accessory to the Elvie™ pump.

It relates to a system allowing a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump. As such, the user does not need a specialised adjustable bra; instead the present system works with all conventional maternity bras. The user also does not have to purchase any larger bras to wear while pumping.

As shown in FIG. **32**, a typical maternity bra **320** comprises a support structure made up of shoulder straps **321** which support the bra **320** on the wearer's shoulders, and a bra band **322** for extending around a user's ribcage, comprising two wings **323** and a central panel or bridge **324**. The straps **321** are typically provided with adjustment mechanisms **325** for varying the length of the straps **321** to fit the bra **320** to the wearer. At the outermost end of each wing, an attachment region **326** is provided. Typically, hooks **327** and loops **328** are provided for securing the bra **320** at the user's back. However, any other suitable attachment mechanism may be used. Alternatively, the attachment region **326** may be provided at the front of the bra **320** in the bridge region **324**, with a continuous wing **323** extending continuously around the wearer's back. Typically, a number of sets of loops **328** are provided to allow for variation in the tightness of the bra **320** on the wearer. While shown as having a separation in FIG. **32**, the wings **323** and bridge **324** may form a single continuous piece in certain designs. Likewise,

while shown with a distinct separation in FIG. **32**, the shoulder straps **321** and the wings **323** may likewise form a single continuous piece.

The maternity bra **320** is further provided with two breast-supporting cups **329** attached to the support structure. The cups **329** define a cup size, which defines the difference in protrusion of the cups **329** from the band **322**. The European standard EN 13402 for Cup Sizing defines cup sizes based upon the bust girth and the underbust girth of the wearer and ranges from AA to Z, with each letter increment denoting a 2 cm difference between the protrusion of the cups **329** from the band **322**. Some manufacturers do vary from these conventions in denomination, and some maternity bras are measured in sizes of S, M, L, XL, etc.

The cups **329** may be stitched to the bra band **321**. At least one of the cups **329**, is in detachable attachment with the corresponding strap **321**. In particular, this is achieved at attachment point **330** where a hook **331** attached to the bra strap **321** engages with a clasp **331** attached to the cup **329**. The hook **331** and the bra strap adjuster **325** are set such that in the closed position, the cup size of the bra **320** fits the wearer's breasts.

In FIG. **32**, the left cup **329** is shown attached to its attachment point **330**, which the right cup **329** is unattached. In this manner, the wearer is able to detach the cup **329** to expose their breast for feeding or for breast pumping. Once this is completed, the cup **329** is reattached and the maternity bra **320** continues to function as a normal bra.

While in the depicted embodiments, a hook **331** is shown on the bra strap **321** and a clasp **332** is shown on the cup **329**, it is appreciated that the provision of these may be reversed, or that alternative attachment mechanisms may be used.

A maternity bra therefore may comprise a support structure comprising shoulder straps and a bra band and a first and a second cup each attached to the support structure to provide a first cup size, at least one cup being at least partially detachable from the support structure at an attachment point.

In other embodiments, the detachable attachment point **330** may be provided at a different location, such as at the attachment between the bra band **322** and the cup **329**. The mechanism for such an attachment point is the same as described above.

A clip has been designed such that it is configured to be attached to the support structure at a position away from the attachment point. This results in the original attachment point being usable, with the clip providing an alternative attachment point to give, in effect, an adjusted cup size.

Alternatively, the clip may also be attachable to the support structure at a plurality of non-discrete positions. This ensures essentially infinite adjustment of the clip position such that the perfect position for the user can be found.

The clip can also extend between an unextended and an extended state, and can attach to the support structure at the attachment point; the first cup size is providable when the at least partially detachable cup is attached to the clip when the clip is an unextended state; the second cup size is providable when the at least partially detachable cup is attached to the clip when the clip is in an extended state. An extendable clip like this allows quick switching between the two states in use.

FIG. **33** depict a clip **335** according to the present invention, along with a clasp **332** shown in isolation from the bra cup **329** it is normally attached to. The clip comprises a first engagement mechanism and at least one second engagement mechanism(s). The clip is attachable in a releasable manner to the support structure at a first position via the first engagement mechanism and attachable in a releasable manner to one of the partially detachable cups via the second engagement mechanism to provide a second cup size different to the first cup size. The clip **335** is provided with a material pathway **336** which receives a portion of the bra strap **321**. In the particular embodiment of these Figures, the clip **335** is substantially U-shaped, with a narrowing profile towards its open end. However, it is appreciated that any other suitable shape with a material pathway may be used, such as an S-shape or E-shape. The clip **335** is designed to be attached to the bra strap **321** in a releasable manner, with the slot **336** acting as a support engaging mechanism. The releasable manner means that the clip **335** may be simply removed from the bra **320** without causing any damage to the functioning of the bra **320**. To enhance the ease of attachment, the clip **335** may be provided with outwardly extending wings **204** which help direct the bra strap **321** into the clip **335**. The clip **335** is further provided with a hook **220** acting as a cup engaging mechanism which can engage with the clasp **332**.

FIG. **33** (*c*) shows the clip **335** being attached to a bra strap **321** in order to provide a second attachment point **337** for the clasp **332** to attach to, and hence to provide a second cup size for the bra **320**. In this particular embodiment, the clip **335** is attached in a portion of strap **321**A below the original attachment point **330** and hence the second attachment point **337** is likewise below the original attachment point. This results in a second cup size larger than the first cup size. In preferred embodiments, as shown in these Figures, the clip **335** engages with the support structure in a direction transverse to the direction in which it engages with the cup.

FIGS. **33** (*d*) and (*e*) show how a wearer is able to move between the first and second cup sizes. In **33**(*d*), the cup **329** is attached at the first attachment point **330** to provide a first cup size. The wearer then disengages the clasp **332** from the hook **331** at the hook **338** at the second engagement point **239**. In this manner, the wearer is easily able to transition between the two cup sizes.

FIGS. **34** and **35** show an alternative design for a clip **340**. This clip **340** is substantially "E-shaped", with a back portion **341** and first, second and 5 third prongs **342**A, **342**B, **342**C extending transverse from this back portion **341**. The three prongs **342**A, **342**B, **342**C are spaced apart along the length of the back portion **341**. The first and third prongs **342**A, **342**C are provided with attachment clips **343**A, **343**B.

These attachment clips **343**A, **343**B can engage with the clasp **332** of a bra to provide the second cup size. Depending upon the orientation of the clip **300**, one or the other of the attachment clips **343**A, **343**B will be used to attach the clasp **332** of the bra. By providing these clips **343**A, **343**B on both of the first and the third prongs **342**A, **342**C the clip is easily reversible so it can be used on either side of the bra. Preferably the clip **340** is also symmetrical, to aid the reversibility of the clip **340**.

FIG. **35** shows the clip **340** attached to a bra. As can be seen, the first and third prongs **342**A, **342**C extend on the front side of the bra strap, with the second prong **342**B extending on the rear side of the bra strap. In this manner, the clip **340** is attached to the strap. In preferable embodiments, a grip-enhancing member **344** such as a number of projections and/or roughened patches can be provided on the second prong **342**B in order to strengthen this grip.

In alternative embodiments, the attachment clip could be provided on the second, centremost prong **342**B. In such an

arrangement, the centremost prong **342**B would be on the outside of the bra, with the first and third prongs **342**A, **342**C on the inside.

The provision of the attachable clip allows maternity bras already owned by the wearer to be quickly transformed into bras with quick switchable double cup size options.

This allows the use of integrated wearable breast pumps which increase the user's required cup size. This allows more design freedom for the breast pump in terms of size and shape, while still allowing the user to discretely pump with the pump held within their bra. By allowing conversion of the user's existing maternity bras, they are not forced to purchase specially designed bras to wear with the pump. The bra is hence normally at the first engagement point **330** when the breast pump device is not being used. As shown in FIG. **33**, the clasp **332** is then engaged by the user to discretely switch between the two configurations, and the user then inserts the pump without any complex adjustment or removal of clothing.

Preferably, the clip will be relatively unobtrusive in size and shape and hence can be left in place when the bra is first put on and used when necessary. To this end, the clip is preferably machine washable without significant damage or degradation.

In some embodiments, the clip may be switchable between positions for engaging with each cup so that a single clip may be used on either side of the bra. To achieve this, the clip is preferably reversible. This may provide the user with a visual indication of which breast has produced milk most recently so switching can take place.

In a preferred embodiment, the first engagement mechanism engages with the support structure in a first direction and the second engagement mechanism engages with the cup in a second direction transverse to the first direction. This increases ease of attachment as with this structure the sideways engagement of the clip to the support structure ensures that the second attachment mechanism is correctly orientated for the cup.

The second engagement mechanism may be one or more of a hook or a snap or a clip. This ensures easy interfacing with the traditional hook and clasp systems already provided on maternity bras.

Preferably the clip further comprises two distinct second engagement mechanisms which can be used interchangeably dependent upon the orientation of the clip. This makes the clip easier to use as it can be quickly switched between each bra strap, and the user does not have to worry which way up to put the clip on.

Preferably, the clip comprises a material pathway with an opening for receiving a portion of the support structure as the first engagement mechanism for securing the clip to the bra. This ensures a quick and simple method for attaching the clip to the bra. In particular, the clip may substantially U-shaped, and the material pathway is between the arms of the U.

Preferably, the clip comprises three prongs extending from a central support, the three prongs arranged as a central prong and two outer prongs so as to receive the support structure on one side of the central prong and on the opposite side of each respective outer prong, at least one prong being provided with the second engagement mechanism. This ensures a strong attachment to the bra and a simple design.

Preferably, both outer prongs are each provided with a respective second engagement mechanism. This ensures that the clip is reversible for easier attachment to the bra.

A method of adjusting the cup size of a maternity bra is provided according to the present invention, comprising: providing a maternity bra comprising: a support structure comprising shoulder straps and a bra band; and a first and second cup each attached to the support structure to provide a first cup size, the at least one cup being detachable from the support structure at an attachment point, providing a clip comprising first and section engagement mechanisms, attaching the first engagement mechanism of the clip in a releasable manner to a first position of the support structure of the maternity bra, attaching one of the detachable cup to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size.

This clip and method allow a user to quickly and simply adjust the cup size of a maternity bra to allow discrete and comfortable insertion and use of an integrated wearable breast pump.

Preferably, the method further comprises the step of inserting a breast pump into the detachable cup. The adjustment of the size of the bra allows the bra to support the breast pump against the user's breast for comfort and ease.

Preferably, the method further comprises the steps of: detaching the first engagement mechanism of the clip from the first position support structure of the maternity bra; attaching the first engagement mechanism of the clip in a releasable manner to a second position of the support structure of the maternity bra; and attaching the other of the detachable cups to the second engagement mechanism of the clip in a releasable manner to provide a second cup size different to the first cup size. This allows the user to use a single clip on either of the cups.

An alternative embodiment may be provided, with an extendable clip **360** as shown in FIG. **36**. In such an embodiment the clip is attached to the hook **331** on the strap **321** in a releasable manner, with the clasp **332** attached to an expandable portion of the clip. The clip is then able to expand between an unexpanded state where the clasp **332** is held in substantially the same position as the first attachment point **330** to provide the first cup size, and an expanded state, where the clasp **332** is held in a second position away from the first attachment point **330** to provide the second cup size.

For example, an elongate clip with first and second opposite ends may be provided. A first attachment point for attaching to the hook **331** is provided at the first end, and a second attachment point for attaching to the clasp **332** is provided at the second end. The elongate clip is hinged between the two ends, such that the clip can be folded between an elongate configuration to a closed configuration where the second end touches the first end. A clasp can be provided on the clip to hold the second end in this closed configuration. Thus, in the closed position the clasp **332** is held in substantially the same location as the first attachment point **330** to provide the first cup size, and in the open position the clasp is held away from the first attachment point **330** to provide the second cup size.

Other extendable clip embodiments are also possible, for example sliding clips or elastic clips.

Additional embodiments of a maternity bra adjuster are provided in FIGS. **37** and **38**. The alternative proposed solution is a small adapter device, which comprises a first portion **370** including a clasp **373** and a second portion **372** including a hook **374**, in which the first and second portions are separated by a small distance **371** in order to provide two different adjustable sizes. The first portion includes a clasp **373** that is designed to attach to the hook on the bra strap **321**. It may also include a top hook **375** positioned underneath the clasp, and a clip **376** on the rear side. The second portion includes a bottom hook **372**.

The clasp **332** that is present on the cup **329** of the maternity bra, may then either engage with the top hook (**321**) to provide a first cup size, and engage with the bottom hook (**332**) to provide a second cup size that is different from the first cup size, as illustrated in FIG. **39**. The user may then discretely switch between a non pumping position, provided by the first cup size, and a second pumping position without any complex adjustment or removal of clothing needed, while using a wearable breast pump system (**100**).

The first portion and second portion may be made of plastic and may be separated by a stretchy material such as elastic or elastomeric material. The first portion may also include a clip on the rear side, the purpose of which is to allow the user to leave the clip attached to the bra for an extended time period.

Section D: Use of Piezo Pump in Wearables

As described in Section A, the breast pump system includes a piezo air pump, resulting in a fully wearable system that delivers a quiet, comfortable and discreet operation in normal use. This section gives further information on the piezo air pump.

In comparison with other pumps of comparable strength, piezo pumps are smaller, lighter and quieter.

Each individual Piezo pump weighs approximately 6 gm and may, with material and design improvements, weigh less than 6 gm.

In operation, the Elvie breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise; tests indicate that it makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

Piezo pumps also have lower current draw, allowing for increased battery life. A piezo pump is therefore ideally suited for wearable devices with its low noise, high strength and compact size. Further, as shown in the breast pump system of FIGS. **7** and **8**, more than one piezo pump may be used.

Whilst a breast pump system is largely described in previous sections, the use of piezo mounted either in series or in parallel can also be implemented in any medical wearable devices or any wearable device. The piezo pump may pump air as well as any liquid.

With reference to FIG. **40**, a diagram illustrating a configuration of two piezo pumps mounted in series is shown.

With reference to FIG. **41**, a diagram illustrating a configuration of two piezo pumps mounted in parallel is shown.

With reference to FIG. **42**, the air pressure generated as a function of time by two piezo pumps mounted in series and two piezo pumps mounted in parallel are compared. In this example, the parallel configuration produces higher flow rate and achieves −100 mmHg negative air pressure faster than the series configuration. In comparison, the series configuration produces lower flow rate and takes slightly longer to reach 100 mmHg. However, the parallel configuration cannot achieve as high as a vacuum as the series configuration and plateaus at −140 mmHg. In comparison, the series configuration is able to generate about −240 mmHg.

A dual configuration is also implemented in which more than one piezo pump is configured such that they can easily switch between a parallel mode and a series mode. This dual configuration would suit wearable devices that would need to achieve either lower or higher pressure faster.

FIG. **43** shows a plot of the air pressure generated as a function of time by two piezo pumps mounted in a dual configuration. In this dual configuration, the piezo pumps first start with a parallel mode in order to benefit from faster flow rate, and then switch to a series mode (as indicated by the switch-over point) when stronger vacuums are required, enabling to save up to 500 ms on cycle time with elastic loads.

Additionally, a piezo pump may be used in combination with a heat sink in order to efficiently manage the heat produced by the wearable pump. This configuration may be used to ensure that the wearable device can be worn comfortably. The heat sink or heat sinks are configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin (especially prolonged contact for greater than 1 minute) are no more than 48° C. and preferably no more than 43° C.

The heat sink may store the heat produced by a piezo pump in order to help diverting the heat produced to another location. This not only ensures that the wearable system can be worn comfortably, but also increases the lifetime of a piezo pump.

FIG. **44** shows a picture of a wearable breast pump housing including multiple piezo pumps (**440**). The breast pump system is wearable and the housing is shaped at least in part to fit inside a bra. By applying a voltage to the piezo pumps, the pressure provided by the pumps increase. The generation of higher pressure by the piezo pumps also means higher heat produced that needs to be managed. Each piezo pump is therefore connected to a heat sink (**441**), such as a thin sheet of copper. The heat sink has a long thermal path length that diverts the heat away from the piezo pump.

The use of a heat sink in combination with a piezo pump is particularly relevant when the wearable device is worn directly or near the body, and where the management of heat induced by the piezo pump is crucial.

A wearable device including a piezo pump may therefore include a thermal cut out, and may allow for excess heat to be diverted to a specific location. The heat sink may be connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere. For example, the wearable system is a breast pump system and the heat sink stores heat, which can then be diverted to warm the breast shield of the breast pump system.

Use cases application include but are not limited to:

Wound therapy;

High degree burns;

Sleep apnoea;

Deep vein thrombosis;

Sports injury.

APPENDIX: SUMMARY OF KEY FEATURES

In this section, we summarise the various features implemented in the Elvie™ pump system. We organize these features into six broad categories:

A. Elvie Breast Pump: General Usability Feature Cluster
B. Elvie Piezo Air Pump Feature Cluster
C. Elvie Milk Container Feature Cluster
D. Elvie IR System Feature Cluster
E. Elvie Bra Clip Feature Cluster
F. Other Features, outside the breast pump context

Drilling down, we now list the features for each category:

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is wearable and includes only two parts that are removable from the pump main housing in normal use.

Feature 2 Elvie is wearable and includes a clear breast shield giving an unobstructed view of the breast for easy nipple alignment.

Feature 3 Elvie is wearable and includes a clear breast shield with nipple guides for easy breast shield sizing.

Feature 4 Elvie is wearable and includes a breast shield that audibly attaches to the housing.

Feature 5 Elvie is wearable and includes a breast shield that attaches to the housing with a single push.

Feature 6 Elvie is wearable and not top heavy, to ensure comfort and reliable suction against the breast.

Feature 7 Elvie is wearable and has a Night Mode for convenience.

Feature 8 Elvie is wearable and includes a haptic or visual indicator showing when milk is flowing or not flowing well.

Feature 9 Elvie is wearable and collects data to enable the mother to understand what variables (e.g. time of day, pump speed etc.) correlate to good milk-flow.

Feature 10 Elvie is wearable and collects data that can be exported to social media.

Feature 11 Elvie is wearable and has a smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 12 A smart bottle that stores the time and/or date of pumping to ensure the milk is used when fresh.

Feature 13 Elvie is wearable and includes a sensor to infer the amount of movement or tilt angle during normal use.

Feature 14 Elvie includes a control to toggle between expressing milk from the left breast and the right breast.

Feature 15 Elvie includes a pressure sensor.

Feature 16 Elvie includes a microcontroller to enable fine tuning between pre-set pressure profiles.

Feature 17 Elvie enables a user to set the comfort level they are experiencing.

Feature 18 Elvie includes a microcontroller to dynamically and automatically alter pump operational parameters.

Feature 19 Elvie automatically learns the optimal conditions for let-down.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is wearable and has a piezo air-pump for quiet operation.

Feature 21 Elvie has a piezo air-pump and self-sealing diaphragm Feature 22 Elvie uses more than one piezo air pump in series.

Feature 23 Elvie is wearable and has a piezo air-pump, a breast shield and a diaphragm that fits directly onto the breast shield.

Feature 24 Elvie is wearable and has a piezo air-pump for quiet operation and a re-useable, rigid milk container for convenience.

Feature 25 Elvie has a piezo-pump for quiet operation and is a connected device.

Feature 26 Elvie uses a piezo in combination with a heat sink that manages the heat produced by the pump.

Feature 27 Elvie is wearable and gently massages a mother's breast using small bladders inflated by air from its negative pressure air-pump.

Feature 28 Elvie is wearable and gently warms a mother's breast using small chambers inflated by warm air from its negative pressure air-pump.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is wearable and includes a re-useable, rigid milk container that forms the lower part of the pump, to fit inside a bra comfortably.

Feature 30 Elvie is wearable and includes a milk container that latches to the housing with a simple push to latch action.

Feature 31 Elvie is wearable and includes a removable milk container with an integral milk pouring spout for convenience.

Feature 32 Elvie is wearable and includes a removable milk container below the milk flow path defined by a breast shield for fast and reliable milk collection.

Feature 33 Elvie is wearable and includes a breast shield and removable milk container of optically clear, dishwasher safe plastic for ease of use and cleaning.

Feature 34 Elvie is wearable and includes various components that self-seal under negative air pressure, for convenience of assembly and disassembly.

Feature 35 Elvie is wearable and includes a spout at the front edge of the milk container for easy pouring.

Feature 36 Elvie is wearable and includes a milk container that is shaped with broad shoulders and that can be adapted as a drinking bottle that baby can easily hold.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the quantity of milk in the container for fast and reliable feedback.

Feature 38 The separate IR puck for liquid quantity measurement.

Feature 39 The separate IR puck combined with liquid tilt angle measurement.

E. Bra Clip Feature

Feature 40 Bra Adjuster.

F. Other Features that can Sit Outside the Breast Pump Context

Feature 41 Wearable device using more than one piezo pump connected in series or in parallel.

Feature 42 Wearable medical device using a piezo pump and a heat sink attached together.

We define these features in terms of the device; methods or process steps which correspond to these features or implement the functional requirements of a feature are also covered.

We'll now explore each feature 1-42 in depth. Note that each feature can be combined with any other feature; any sub-features described as 'optional' can be combined with any other feature or sub-feature.

A. Elvie Breast Pump: General Usability Feature Cluster

Feature 1 Elvie is Wearable and Includes Only Two Parts that are Removable from the Pump Main Housing in Normal Use

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a rigid or non-collapsible milk container;

and in which the breast pump system includes only two parts that are directly removable from the housing in normal use or normal dis-assembly: the breast shield and the rigid, non-collapsible milk container.

Optional:

The only parts of the system that come into contact with milk in normal use are the breast shield and the milk container.

Milk only flows through the breast shield and then directly into the milk container.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings, in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

No other parts are removable from the breast shield, apart from the flexible diaphragm.

The milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

The milk container mechanically or magnetically latches to the housing.

The milk container is released by the user pressing a button on the housing.

The milk container includes a removable cap and a removable valve that is seated on the lid.

In normal use, the milk container is positioned entirely within a bra.

No other parts are removable from the milk container, apart from the cap and the valve.

All parts that are user-removable in normal use are attached to either the breast shield or the milk container.

Audible or haptic feedback confirms the pump system is properly assembled for normal use with the milk container locked to the housing and the breast shield locked to the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 2 Elvie is Wearable and Includes a Clear Breast Shield Giving an Unobstructed View of the Breast for Easy Nipple Alignment

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel, shaped to receive a nipple, providing to the mother placing the breast shield onto her breast a clear and unobstructed view of the nipple when positioned inside the nipple tunnel, to facilitate correct nipple alignment.

Optional:

The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is completely out, of or separated from, the housing.

The breast shield is configured to provide to the mother a clear and unobstructed view of the nipple when the breast shield is partially out of, or partially separated from, the housing.

Entire breast shield is substantially transparent.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

The milk container mechanically or magnetically latches to the housing.

The milk container is released by the user pressing a button on the housing.

The milk container includes a removable cap and a removable valve that is seated on the lid.

In normal use, the milk container is positioned entirely within a bra.

Feature 3 Elvie is Wearable and Includes a Clear Breast Shield with Nipple Guides for Easy Breast Shield Sizing

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield including a substantially transparent nipple tunnel shaped to receive a nipple, the nipple tunnel including guide lines that define the correct spacing of the nipple from the side walls of the nipple tunnel.

Optional:

The guide lines run generally parallel to the sides of the nipple placed within the nipple tunnel.

Breast shield is selected by the user from a set of different sizes of breast shield to give the correct spacing.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 4 Elvie is Wearable and Includes a Breast Shield that Audibly Attaches to the Housing.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield that is attachable to the housing with a mechanism that latches with an audible click when the breast shield is slid on to or against the housing with sufficient force.

Optional:

The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

Breast shield is removable from the housing with an audible click when the breast shield is pulled away from the housing with sufficient force.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around the nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 5 Elvie is Wearable and Includes a Breast Shield that Attaches to the Housing with a Single Push

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield configured to attach to the housing with a single, sliding push action.

Optional:

The breast shield is configured to slide onto or against the housing in a direction parallel to the long dimension of a nipple tunnel in the breast shield.

The single push action overcomes a latching resistance.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into a nipple tunnel in the breast shield to position a diaphragm housing portion of the breast shield at the top of the breast.

Housing is configured to slide onto the breast shield when the breast shield has been placed onto a breast using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Breast shield includes or operates with a flexible diaphragm that (a) flexes when negative air pressure is applied to it by an air pump system in the housing, and (b) transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

The edge of the flexible diaphragm seals, self-seals, self-energising seals, or interference fit seals against the housing when the breast shield attaches to the housing.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel includes on its lower surface an opening through which expressed milk flows.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

A milk container attaches to a lower surface of the housing and forms the base of the breast pump system in use.

The milk container mechanically or magnetically latches to the housing.

The milk container is released by the user pressing a button on the housing.

The milk container includes a removable cap and a removable valve that is seated on the lid.

In normal use, the milk container is positioned entirely within a bra.

Feature 6 Elvie is Wearable and not Top Heavy, to Ensure Comfort and Reliable Suction Against the Breast

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism

(b) and a breast shield;

(c) a milk container;

and in which the centre of gravity of the pump system is, when the milk container is empty, substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through a nipple tunnel or filling point on a breast shield, so that the device is not top-heavy for a woman using the pump.

Optional:

The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

In which the centre of gravity only moves lower during use as the milk container gradually receives milk, which increases the stability of the pump inside the bra.

In which milk only passes downwards when moving to the milk container, passing through the nipple tunnel and then through an opening in the lower surface of the nipple tunnel directly into the milk container, or components that are attached to the milk container.

System is configured so that its centre of gravity is no more than 60 mm up from the base of the milk container also below the top of the user's bra cup.

In which the pumping mechanism and the power supply for that mechanism are positioned within the housing to provide a sufficiently low centre of gravity.

In which the pumping mechanism is one or more piezo air pumps, and the low weight of the piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

In which the pumping mechanism is one or more piezo air pumps, and the small size of the piezo air pumps enables the components in the housing to be arranged so that the centre of gravity is substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

In which the pumping mechanism is one or more piezo air pumps, and the low weight of the battery or batteries needed to power that piezo air pumps enables the centre of gravity to be substantially at or below (i) the half-way height line of the housing or (ii) the horizontal line that passes through the nipple tunnel or filling point on the breast shield.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 7 Elvie is Wearable and has a Night Mode for Convenience

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) an illuminated control panel;

(c) a control system that reduces or adjusts the level or colour of illumination of the control panel at night or when stipulated by the user.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Control system is implemented in hardware in the pump itself using a 'night mode' button.

Control system is implemented in software within a connected device app running on the user's smartphone.

Control system is linked to the illumination level on a connected device app., so that when the connected app is in 'night mode', the illuminated control panel is also in 'night mode', with a lower level of illumination, and when the illuminated control panel on the housing is in 'night mode', then the connected app is also in 'night mode'.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast. The pumping mechanism is one or more piezo air pumps, selected for quiet operation.

Feature 8 Elvie is Wearable and Includes a Haptic or Visual Indicator Showing when Milk is Flowing or not Flowing Well

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a milk container that is configured to be concealed within a bra and is hence not visible to the mother in normal use;

(c) a visual and/or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

Optional:

A haptic and/or visual indicator indicates if the pump is operating correctly to pump milk, based on whether the quantity and/or the height of the liquid in the container above its base is increasing above a threshold rate of increase

The visual indicator is a row of LEDs that changes appearance as the quantity of liquid increases.

The haptic and/or visual indicator provides an indication of an estimation of the flow rate.

The visual indicator provides a colour-coded indication of an estimation of the flow rate.

The visual indicator provides an indication of how much of the container has been filled.

The visual indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.

The haptic indicator is part of a user interface in a connected, companion application, running on a smartphone or other personal device, such as a smart watch or smart ring.

A sub-system measures or infers the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

A sub-system measures or infers the angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

A haptic and/or visual indicator indicates if the amount of milk in the milk container has reached a preset quantity or level.

A haptic and/or visual indicator indicates if there is too much movement of the breast pump system for viable operation.

Milk container is attached to the lower part of the housing and forms the base of the breast pump system.

Milk container is made of transparent material.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 9 Elvie is Wearable and Collects Data to Enable the Mother to Understand What Variables (e.g. Time of Day, Pump Speed Etc.) Correlate to Good Milk-Flow

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a measurement sub-system that measures or infers milk flow into the milk container;

and in which the measurement sub-system provides data to a data analysis system that determines metrics that correlate with user-defined requirements for milk-flow rate or milk expression.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

User-defined requirement is to enhance or increase milk-flow.

User-defined requirement is to reduce milk-flow.

The data analysis system analyses data such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.

The data analysis system determines metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

The data analysis system determines metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.

measurement sub-system measures or infers the quantity and/or the height of the liquid in the container above its base.

Measurement sub-system measures or infers angle the top surface of the liquid in the container makes with respect to a baseline, such as the horizontal.

Data analysis system gives recommended metrics for improving milk flow

Data analysis system gives recommended metrics for weaning.

Data analysis system gives recommended metrics for increasing milk supply (e.g. power pumping).

Data analysis system gives recommended metrics if an optimal session start time or a complete session has been missed.

Data analysis system leads to automatic setting of metrics for the pumping mechanism, such as pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session.

Data analysis system enables sharing across large numbers of connected devices or apps information that in turn optimizes the milk pumping or milk weaning efficacy of the breast pump.

Metrics include the specific usage of the connected device by a woman while using the pump (for example by the detection of vision and/or audio cues).

The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container.

The measurement sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

The measurement sub-system includes or communicates with an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently

still to permit the measurement sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 10 Elvie is Wearable and Collects Data that can be Exported to Social Media.

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) a milk container;

(c) a data sub-system that collects and provides data to a connected device or remote application or remote server;

(d) and in which the collected data, in whole or in part, is used by a data analysis system that provides inputs to a social media or community function or platform.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.

The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Data analysis system is local to the breast pump system, or runs on a connected device, such as a smartphone, or is on a remote server or is on the cloud, or is any combination of these.

The social media or community function or platform organizes the collected data into different profiles.

The social media or community function or platform enables a user to select a matching profile from a set of potential profiles.

each profile is associated with a specific kind of milk expression profile, and provides information or advice that is specifically relevant to each milk expression profile.

Information or advice includes advice on how to increase milk expression by varying parameters, such as time of milk expression, frequency of a milk expression session, pump speed, length of a single pumping session, vacuum level, cycle times, changing profile of pump speed over a single pumping session and any other parameter that can be varied by a mother to help her achieve her milk expression goals.

The application is connected to other applications residing on the connected device, such as a fitness app.

The collected data includes data received from other connected apps.

The collected data is anonymised before it is shared.

The sub-system includes a wi-fi connectivity component for direct connectivity to a remote server.

The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 11 Elvie is Wearable and has a Smart Bottle that Stores the Time and/or Date of Pumping to Ensure the Milk is Used when Fresh

A breast pump system including a pumping mechanism and a milk container and including:

(a) a housing including the pumping mechanism;

(b) a milk container;

(c) and in which the milk container or any associated part, such as a lid, includes a memory or tag that is automatically programmed to store the time and/or date it was filled with milk.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Memory or tag is programmed to store the quantity of milk in the milk container.

Memory or tag stores the milk expiry date.

Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.

System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.

Clock is in the housing.

Clock is in the milk container.

Milk container includes a display that shows the time and/or date it was filled with milk.

Milk container includes a display that shows the quantity of milk that it was last filled with milk.

Milk container includes a display that shows whether the left or right breast was used to fill the milk container.

Memory or tag is connected to a data communications sub-system.

Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone, and have the time and/or date that container was filled with milk, displayed on the reader device.

Reader device shows the time and/or date a specific milk container was filled with milk.

Reader device shows the quantity of milk that a specific milk container was last filled with.

Reader device shows the time and/or date and/or quantity that each of several different milk containers were filled with.

Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.

A sub-system measures or infers milk flow into the milk container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/Tr the height of the liquid in the container.

The sub-system is in the housing.

Milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 12 a Smart Bottle that Stores the Time and/or Date of Pumping to Ensure the Milk is Used when Fresh.

A smart bottle or container that includes or is associated with a memory or a tag that is programmed to store the date and time it is filled using data from a pump or a connected device, such as a smartphone.

Optional:

The container includes wireless connectivity and connects to a companion app.

The memory or tag includes an NFC chip and is read using a NFC reader.

The memory or tag stores also an expiry date.

Memory or tag stores a record of the temperature of the milk or the ambient temperature around the milk, and calculates an expiry date using that temperature record.

The memory or tag stores also the quantity of milk stored.

System includes a clock and writes the time and/or date the milk container was filled with milk to the memory or tag on the milk container.

Clock is in the housing.

Clock is in the container.

Milk container includes a display that shows the time and/or date it was filled with milk.

Milk container includes a display that shows the quantity of milk that it was last filled with milk.

Milk container includes a display that shows whether the left or right breast was used to fill the milk contained.

Milk container includes a display that shows the expiry date.

memory or tag is connected to a data communications sub-system.

Memory or tag is a remotely readable memory or tag, such as a NFC tag, enabling a user to scan the milk container with a reader device, such as a smartphone.

Reader device shows the time and/or date a specific milk container was filled with milk.

Reader device shows the quantity of milk that a specific milk container was last filled with.

Reader device shows the time and/or date and/or quantity that each of several different containers were filled with.

Reader device shows whether the left or right breast was used to fill the milk contained in a specific milk container.

Reader device shows the expiry date.

Container includes wireless connectivity and connects to a companion application.

An application tracks status of one or more smart containers and enables a user to select an appropriate smart container for a feeding session.

The pump is wearable.

The pump is in a housing shaped to fit inside a bra and the container is a milk container that is connected to the housing and is positioned to form the base of the housing.

Container is used for liquids other than milk.

Feature 13 Elvie is Wearable and Includes a Sensor to Infer the Amount of Movement or Tilt Angle During Normal Use.

A breast pump system including:

(a) a housing;

(b) a milk container;

(c) the housing including a sensor, such as an accelerometer, that measures or determines the movement and/or tilt angle of the housing, during a pumping session and automatically affects or adjusts the operation of the system depending on the output of the sensor.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by warning or alerting the mother of a potential imminent spillage (e.g. from milk flowing back out of a breast shield) using an audio, or visual or haptic alert, or a combination of audio, haptic and visual alerts.

If the tilt angle of the housing exceeds a threshold, then the system automatically adjusts the operation of the system by stopping the pump to prevent spillage.

When the tilt angle of the housing reduces below the threshold, the system automatically adjusts the operation of the system by causing pumping to resume automatically.

If the tilt angle of the housing exceeds a threshold, then the system automatically affects the operation of the system by providing the mother with an alert to change position.

The container includes an optically clear region.

There are one or more light emitters and detectors positioned in the base of the housing, the light emitters and receivers operating as part of a sub-system that measures or infers the tilt angle of the milk in the container.

The sub-system measures the quantity of liquid in the milk container and also takes the measured tilt angle of the housing into account.

If the tilt angle is above a certain threshold, the system ignores the quantity of liquid measured.

The sub-system derives or infers the mother's activity, such as walking, standing or lying activities, from the sensor.

The milk container is a re-useable milk container that when connected to the housing is positioned to form the base of the housing.

Sub-system stores a time-stamped record of movement and/or tilt angles of the housing in association with milk flow data.

System includes a breast shield that attaches to the housing.

System includes a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 14 Elvie Includes a Control to Toggle Between Recording Whether Milk is being Expressed from the Left Breast and the Right Breast.

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a control interface that the user can select to indicate or record if milk is being expressed from the left or the right breast.

Optional:

Control interface is a physical interface on the housing.

Control interface is a single button on the housing.

Control interface is from an application running on a device, such as a smartphone or smart ring.

Visual indicators on the housing indicate whether the breast pump system is being set up the left or the right breast.

The visual indicator for the left breast is on the right-hand side of the housing, when viewed from the front; and the visual indicator for the right breast is on the left-hand side of the housing, when viewed from the front.

The housing includes a button labeled to indicate the left breast and a button labeled to indicate the right breast, that are respectively illuminated to indicate from which breast the milk is being expressed.

Breast pump system is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 15 Elvie Includes a Pressure Sensor.

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) an air pressure sensor configured to measure the negative pressure delivered by the negative air-pressure mechanism and (iii) a measurement sub-system that measures or infers milk flow or milk volume.

Optional:

The system also includes a control sub-system that combines or relates the air-pressure measurements with the milk flow or milk volume measurements

The control sub-system automatically adjusts the negative air-pressure to give the optimal milk flow or milk volume.

The control sub-system automatically adjusts the negative air-pressure during a pumping session to give the optimal milk flow or milk volume within comfort constraints defined by the user.

The air pressure sensor detects pressure created by the pumping mechanism.

Sensor is a piezo air pressure sensor

Air pressure sensor measures the negative air pressure during a normal milk expression session.

Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that it deliver consistent performance over time.

Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to vary the operation of the pumping mechanism so that different pumping mechanisms in different breast pump systems all deliver consistent performance

Air pressure sensor measures the negative air pressure during a calibration session, and the system uses the results to determine if the pumping mechanism is working correctly, within tolerance levels.

The operation of the pumping mechanism is varied by altering the duty or pump cycle.

The operation of the pumping mechanism is varied by altering the voltage applied to the pumping mechanism.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 16 Elvie Includes a Microcontroller to Enable Fine Tuning Between Pre-Set Pressure Profiles

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to cause the pumping mechanism to deliver various pre-set pressure profiles and to permit the user to manually vary the pressure to a value or values that are in-between the values available from a pre-set pressure profile.

Optional:

The user manually varies the pressure using a control interface on a housing of the breast pump system

The user manually varies the pressure using a control interface on an application running on a wireless device such as a smartphone that is wirelessly connected to the breast pump system.

The user manually varies the pressure by altering a control parameter of the pumping mechanism.

The user manually varies the pressure by altering the duty cycle or timing of the pumping mechanism.

The user manually varies the pressure by altering the voltage applied to the pumping mechanism.

The system includes an air pressure sensor configured to measure the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Pressure profile defines one or more maximum negative air pressure levels.

Pressure profile defines one or more maximum negative air pressure levels, each for a pre-set time.

Pressure profile defines one or more cycle time.

Pressure profile defines peak flow rate.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light

detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 17 Elvie Enables a User to Set the Comfort Level they are Experiencing

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to control the pumping mechanism and to permit the user to manually indicate the level of comfort that they are experiencing when the system is in use.

Optional:

The user manually indicates the level of comfort that they are experiencing using a touch or voice-based interface on a housing of the breast pump system

The user manually indicate the level of comfort that they are experiencing using a touch or voice-based interface on an application running on a wireless device, such as a smartphone, that is wirelessly connected to the breast pump system.

The system stores user-indicated comfort levels together with associated parameters of the pumping system.

The system is a connected device and a remote server stores user-indicated comfort levels together with associated parameters of the pumping system.

The parameters of the pumping system include one or more of: pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.

System automatically varies parameters of the pumping system and then enables the user to indicate which parameters are acceptable.

System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 18 Elvie Includes a Microcontroller to Dynamically and Automatically Alter Pump Operational Parameters

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to automatically change one or more parameters of the pumping mechanism, and to automatically measure or relate milk expression data as a function of different values of one or more of these parameters.

Optional:

The milk expression data includes one or more of the following: milk expression rate or quantity; comfort; optimal pumping mode; optimal pumping mode given remaining battery power.

The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters.

The system automatically calculates or identifies the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold.

The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user.

The system displays the parameters of the pumping mechanism that correlate with maximum milk expression rate or quantity to the user and enables the user to manually select those parameters if they are acceptable.

Parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.

System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

Feature 19 Elvie Automatically Learns the Optimal Conditions for Let-Down

A breast pump system including (i) a pumping mechanism that applies negative air-pressure and (ii) a microcontroller programmed to dynamically change one or more parameters of the pumping mechanism, and to automatically detect the start of milk let-down.

Optional:

The microcontroller is programmed to dynamically change one or more parameters of the pumping mechanism, to enable it to learn or optimize the parameters relating to milk let-down.

The system automatically calculates or identifies or learns the parameters of the pumping mechanism that correlate with the quickest start of milk let-down.

The system automatically calculates or identifies or learns the parameters of the pumping mechanism that corre-

late with the quickest start of milk let-down and uses that set of parameters if the comfort experienced by the user when those parameters are used is above a threshold or are otherwise acceptable to the user.

The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down to the user.

The system displays the parameters of the pumping mechanism that correlate with the quickest start of milk let-down and enables the user to manually select those parameters if they are acceptable.

parameters of the pumping mechanism includes pumping strength, peak negative air pressure; flow rate; voltage applied to the pumping mechanism; duty or timing cycle of the pumping mechanism.

System includes an air pressure sensor that measures the negative air pressure delivered by the pumping mechanism.

The air pressure sensor is a piezo air pressure sensor.

Pumping mechanism is a piezo air pump.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a flexible diaphragm that seals, self-seals, self-energising seals or interference fit seals against a diaphragm housing that forms part of a breast shield.

Breast pump system is wearable and includes a housing that is shaped at least in part to fit inside a bra.

Breast pump system includes a milk container and a measurement sub-system that automatically measures the quantity of milk in the milk container.

The measurement sub-system includes one or more light emitters and one or more light detectors, operating as part of a sub-system that measures or infers the quantity of the milk in the container and/or the height of the milk in the container above its base, and in which the light detectors detect and measure the intensity of the light from the emitters that has been reflected from the surface of the milk.

B. Elvie Piezo Air Pump Feature Cluster

Feature 20 Elvie is Wearable and has a Piezo Air-Pump for Quiet Operation

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a separate, deformable diaphragm to generate negative air pressure.

Optional:

The deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The closed system is separated from a 'milk' side by a flexible diaphragm.

Deformable diaphragm is removably mounted against a part of a breast shield.

Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.

Deformable diaphragm is not physically connected to the piezo air-pump.

Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield

Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

The piezo pump is fed by air that passes through an air filter.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 21 Elvie has a Piezo Air-Pump and Self-Sealing Diaphragm

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that is part of a closed loop system that drives, a physically separate, deformable, self-sealing diaphragm, to generate negative air pressure.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The closed system is separated from a 'milk' side by the flexible diaphragm.

Deformable diaphragm is removably mounted against a part of a breast shield.

Deformable diaphragm is a unitary or one-piece object that is removably mounted against a part of a breast shield.

Deformable diaphragm is not physically connected to the piezo air-pump.

Piezo air-pump is a closed loop air-pump that drives a physically separate and remote deformable diaphragm that removably fits directly onto the breast shield.

Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in

the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

The piezo pump is fed by air that passes through an air filter.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 22 Elvie Uses More than One Piezo Air Pump in Series

A breast pump system including:

(a) a housing;

(b) multiple piezo air-pumps in the housing that drives a deformable diaphragm inside the housing to generate negative air pressure; in which the multiple piezo air-pumps can be operated at different times in series-connected and in parallel-connected modes.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Parallel connected mode is used during a first part of a pumping cycle to reach a defined negative air pressure more quickly than series connected mode would, and then the system switches to a series connected mode to reach a greater negative air pressure than series connected mode can reach.

An actuator switches the system from parallel-connected piezo pump mode to series-connected piezo pump mode.

Each piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

Each piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

Each piezo pump is fed by air that passes through an air filter.

Each piezo air pump forms part of a closed or closed loop system.

Each piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

The piezo-air pumps are a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Feature 23 Elvie is Wearable and has a Piezo Air-Pump, a Breast Shield and a Diaphragm that Fits Directly onto the Breast Shield

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a breast shield that attaches to the housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm that fits directly onto the breast shield.

Optional:

Deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Piezo air pump forms part of a closed or closed loop system.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

Piezo air pump is position at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum. power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise. The piezo pump is fed by air that passes through an air filter.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Feature 24 Elvie is Wearable and has a Piezo Air-Pump for Quiet Operation and a Re-Useable, Rigid Milk Container for Convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra;

(b) a piezo air-pump in the housing;

(c) and a re-useable, rigid or non-collapsible milk container that when connected to the housing forms an integral part of the housing and that is also removable from the housing.

Optional:

Piezo air pump forms part of a closed or closed loop system.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The closed system is separated from a 'milk' side by a flexible diaphragm.

A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

The deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

Feature 25 Elvie has a Piezo-Pump for Quiet Operation and is a Connected Device

A breast pump system including

(a) a housing;

(b) a piezo air-pump in the housing;

(c) a milk container;

(d) a data connectivity module that enables data collection relating to the operation of the piezo air-pump and transmission of that data to a data analysis system.

Optional:

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Transmission is to an application running on a connected device such as a smartphone, or a server, or the cloud.

The data collection and transmission relates to any other operational data of the system.

Piezo air pump forms part of a closed or closed loop system.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

The closed system is separated from a 'milk' side by a flexible diaphragm.

A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

Deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

A sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with the data connectivity module.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

The data analysis system analyses metrics such as any of the following: amount of milk expressed over one or more sessions, rate at which milk is expressed over one or more sessions, profile of the rate at which milk is expressed over one or more sessions.

The data analysis system analyses metrics such as any of the following: pump speed, length of a single pumping session, negative air pressure or vacuum level, peak negative air pressure or vacuum level, pump cycle time or frequency, changing profile of pump speed over a single pumping session time of day.

The data analysis system analyses metrics such as any of the following: amount and type of liquids consumed by the mother, state of relaxation of the mother before or during a session, state of quiet experienced by the mother before or during a session, what overall milk expression profile the mother most closely matches.

Feature 26 Elvie Uses a Piezo in Combination with a Heat Sink that Manages the Heat Produced by the Pump.

A breast pump system including:

(a) a housing;

(b) a piezo air-pump in the housing that drives a deformable diaphragm inside the
housing to generate negative air pressure;

(c) a heat sink to manage the heat produced by the piezo-air pump to ensure it can be worn comfortably.

Optional:

The heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48° C. and preferably no more than 43° C.

The breast pump is wearable and the housing is shaped at least in part to fit inside a bra.

Heat sink is connected to an air exhaust so that air warmed by the piezo pumps vents to the atmosphere.

Heat sink warms a breast shield.

Piezo air pump forms part of a closed or closed loop system.

Piezo air pump is positioned at or close to the base of the housing.

There are two or more piezo air pumps.

There are two or more piezo air pumps, each connected to its own or a shared heat sink.

There are two or more piezo air pumps mounted in a series arrangement.

There are two or more piezo air pumps mounted in a parallel arrangement.

The piezo-air pump is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

The piezo air-pump is a closed loop negative air-pressure system that drives a physically separate and remote deformable, self-sealing diaphragm that removably fits directly onto the breast shield.

The closed system is separated from a 'milk' side by a flexible diaphragm.

A deformable diaphragm inside the housing is driven by negative air pressure generated by the piezo pump.

The deformable diaphragm is a flexible generally circular diaphragm that sits over a diaphragm housing that is an integral part of a breast shield.

The deformable diaphragm is removable from the diaphragm housing for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

Nipple tunnel in the breast shield includes an opening on its lower surface that is positioned through which expressed milk flows directly into the milk container.

The piezo pump delivers in excess of 400 mBar (40 kPa) stall pressure and 1.5 litres per minute free air flow.

The piezo air pump weighs less than 10 gm, and may weigh less than 6 gm.

In operation, the breast pump system makes less then 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

In operation, the breast pump system makes approximately 24 dB noise at maximum power and 22 dB at normal power, against a 20 dB ambient noise.

Feature 27 Elvie is Wearable and Gently Massages a Mother's Breast Using Small Bladders Inflated by Air from its Negative Pressure Air-Pump

A breast pump system including:

(a) a housing;

(b) an air-pump in the housing that drives a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides air to regularly or sequentially inflate one or more air bladders or liners that are configured to massage one or more parts of the breast.

Optional:

Air-pump is a piezo pump.

Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.

Bladders or liners are formed in a breast shield that attaches to the housing.

Feature 28 Elvie is wearable and gently warms a mother's breast using small Chambers Inflated by Warm Air from its Negative Pressure Air-Pump

A breast pump system including:

(a) a housing;

(b) an air-pump, such as a piezo pump, in the housing that drive a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast;

(c) in which the air pump also provides warm air to regularly or sequentially inflate one or more air chambers that are configured to apply warmth to one or more parts of the breast.

Optional:

Breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.

The air chamber is a deformable diaphragm positioned on a breast shield that attaches to the housing.

C. Elvie Milk Container Feature Cluster

Feature 29 Elvie is Wearable and Includes a Re-Useable, Rigid Milk Container that Forms the Lower Part of the Pump, to Fit Inside a Bra Comfortably

A wearable breast pump system configured including:

(a) a housing shaped at least in part with a curved surface to fit inside a bra and including a pumping mechanism;

(b) and a re-useable rigid or non-collapsible milk container that when connected to the housing forms an integral, lower part of the housing, with a surface shaped to continue the curved shape of the housing, so that the pump system can be held comfortably inside the bra.

Optional:

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is attached to the housing with a push action.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture, spout or lid that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump mechanism to ensure that negative air-pressure is not applied to the milk container.

The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 30 Elvie is Wearable and Includes a Milk Container that Latches to the Housing with a Simple Push to Latch Action

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that is attachable to the housing with a mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

Optional:

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Milk container, when connected to the housing, forms an integral, lower part of the housing and that is removable from the housing with a release mechanism that can be operated with one hand.

Mechanism that releasably attaches or latches is a mechanical or magnetic mechanism.

Mechanical mechanism includes flanges on the top of the milk container, or the sealing plate that seals the opening to the milk contained, that engage with and move past a surface to occupy a latched position over that surface when the milk container is pressed against the housing to lock into the housing.

The housing includes a button that when pressed releases the milk container from the housing by flexing the surface away from the flanges so that the flanges no longer engage with and latch against the surface.

Mechanism that attaches or latches the milk container into position does so with an audible click.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing by releasing the latch and moving the housing off the milk container.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 31 Elvie is Wearable and Includes a Removable Milk Container with an Integral Milk Pouring Spout for Convenience

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a re-useable milk container that is connected to the housing with a surface shaped to continue the curved or breast-like shape of the pump, so that the pump can be held comfortably inside a bra and where the milk container includes a pouring spout for pouring milk.

Optional:

Spout is integral to the milk container.

Spout is integral to a removable lid to the milk container.

Spout is positioned at or close to the front edge of the milk container.

Spout is removable from the container, such as by clipping off the container.

A teat is attachable to the spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

The pumping mechanism is a closed loop negative air-pressure system that applies negative pressure to a region surrounding a woman's breast to pump milk form that breast.

Feature 32 Elvie is Wearable and Includes a Removable Milk Container Below the Milk Flow Path Defined by a Breast Shield for Fast and Reliable Milk Collection

A wearable breast pump system including:

(a) a housing including a pumping mechanism, the housing being shaped at least in part to fit inside a bra;

(b) and a breast shield including a nipple tunnel shaped to receive a nipple, and including an opening that defines the start of a milk flow path;

(c) a re-useable milk container that when connected to the housing is positioned entirely below the opening or the milk flow path, when the breast pump is positioned or oriented for normal use.

Optional:

The milk container includes an aperture that sits directly underneath the opening in the nipple tunnel in the breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.

Milk flows from the opening directly into the milk container.

Milk flows from the opening directly into the milk container.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against the opening in the breast shield, and milk flows under gravity through the opening into the milk container.

Milk flows from the opening directly onto a valve that is attached to the milk container, the valve closing whilst there is sufficient negative air pressure in the volume of air between the valve and the breast shield opening, and then opening to release the milk into the container when the air pressure rises sufficiently.

Milk flows from the opening directly onto a valve that is attached to a spout, that is in turn attached to the milk container.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

A flexible rubber or elastomeric valve is mounted onto the milk container cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container, and milk flows towards and is retained by the duck bill valve whilst the valve is closed, and flows past the valve into the milk container when the negative air pressure is released and the valve opens.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The two removable parts are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Feature 33 Elvie is Wearable and Includes a Breast Shield and Removable Milk Container of Optically Clear, Dishwasher Safe Plastic for Ease of Use and Cleaning

A breast pump system including:

(a) a housing including a pumping mechanism;

(b) and a breast shield defining a region shaped to receive a nipple, the region defining the start of a milk flow path;

(c) a re-useable, rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the breast shield and the milk container are made substantially of an optically clear, dishwasher safe material.

Optional:

The material is a polycarbonate material, such as Tritan™.

breast pump system is wearable and the housing is shaped at least in part to fit inside a bra.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield operates with a flexible diaphragm that flexes when negative air pressure is applied to it by an air pump system in the housing, and transfers that negative air-pressure to pull the breast and/or nipple against the breast shield to cause milk to be expressed.

Flexible diaphragm is removable from a diaphragm housing portion of the breast shield for cleaning.

Diaphragm housing includes an air hole that transfers negative air pressure to a nipple tunnel in the breast shield, the negative air pressure arising when the diaphragm moves away from the diaphragm housing and towards the housing, and the negative air pressure in the nipple tunnel pulling the breast and/or nipple against the breast shield to cause milk to be expressed.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Feature 34 Elvie is Wearable and Includes Various Components that Self-Seal Under Negative Air Pressure, for Convenience of Assembly and Disassembly

A wearable breast pump system including:

(a) a housing shaped at least in part to fit inside a bra and including an air pumping mechanism;

(b) a breast shield;

(c) a diaphragm that flexes in response to changes in air pressure caused by the air pumping mechanism and that seals to the breast shield;

(d) a re-useable milk container that seals to the breast shield;

and in which either or both of the diaphragm and the re-useable milk container substantially self-seal under the negative air pressure provided by the pumping mechanism.

Optional:

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

The 1 way valve is attached to the milk container, or a lid or spout of the milk container with an interference fit and is readily removed in normal use for separate cleaning.

The diaphragm partly or wholly self-seals to the breast shield under the negative air pressure provided by the pumping mechanism.

The diaphragm partly or wholly self-seals to the housing under the negative air pressure provided by the pumping mechanism.

The diaphragm is attached to the diaphragm housing using elastomeric or rubber latches and is readily removed in normal use for separate cleaning.

The breast shield and milk container are each pressed or pushed into engagement with the housing.

The breast shield and milk container are each pressed or pushed into a latched engagement with the housing.

The breast shield and milk container are each insertable into and removable from the housing using an action confirmed with an audible sound, such as a click.

Breast shield is a one-piece item including a generally convex surface shaped to fit over a breast and a nipple tunnel shaped to receive a nipple.

Breast shield is generally symmetrical about a centre-line running from the top to the bottom of the breast shield when positioned upright for normal use.

Breast shield is configured to be rotated smoothly around a nipple inserted into the nipple tunnel to position a diaphragm housing portion of the breast shield at the top of the breast.

Breast shield slides into the housing using guide members.

Housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

Breast shield latches into position against the housing.

Breast shield latches into position against the housing when spring plungers, such as ball bearings in the housing locate into small indents in the breast shield.

Breast shield latches into position against the housing using magnets.

Feature 35 Elvie is Wearable and Includes a Spout at the Front Edge of the Milk Container for Easy Pouring

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a milk container that forms an integral part of the housing;

(c) a re-useable pouring spout that is positioned at or close to the front edge of the milk container.

Optional:

Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigeratable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.

Spout is integral to a removable lid to the milk container.

Spout is removable from the container, such as by clipping off the container.

A teat is attachable to the spout.

By placing the spout at or close to the front edge of the milk container, the milk container fully empties more readily than where the spout is placed in the middle of the lid of a milk container.

The spout sits generally under an opening in the breast shield spout or nipple tunnel through which expressed milk flows.

The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Feature 36 Elvie is Wearable and Includes a Milk Container that is Shaped with Broad Shoulders and that can be Adapted as a Drinking Bottle that Baby can Easily Hold

A wearable breast pump system configured as a single unit and including:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) a breast shield;

(c) a milk container that is removable from the housing and is shaped or configured to also serve as a drinking bottle that is readily held by a baby because it is wider than it is tall.

Optional:

Teat is attachable directly to the milk container.

Pouring or drinking spout is integral to the milk container.

The shoulders are at least 2 cm in width, and the neck is no more than 1 cm in height, to enable a baby to readily grip and hold the container when feeding from the milk in the container.

Spout/teat/straw resides near the edge of the container's rim.

Milk container is a multifunctional bottle, operating as both a storage container to contain milk that is being expressed, as well as a refrigertable and freezable storage bottle for that milk, as well as a bottle from which that milk can be drunk by a baby.

The re-useable milk container includes a 1 way valve that self-seals against a conduit from the breast shield and allows milk to pass into the container but not spill out, and in which the valve (a) closes and (b) partly or wholly self-seals against the conduit under the negative air pressure provided by the pumping mechanism.

The milk container includes an aperture, spout or lid that self-seals under the negative air-pressure from the pumping mechanism against an opening in a breast shield, and milk flows under gravity through the opening into the milk container.

Spout is integral to the milk container.

Spout is integral to a removable lid to the milk container.

Spout is positioned at or close to the front edge of the milk container.

Spout is removable from the container, such as by clipping off the container.

A teat is attachable to the spout.

A flexible rubber or elastomeric valve is mounted onto the cap or spout and includes a rubber or elastomeric duck-bill valve that stays sealed when there is negative air-pressure being applied by the air pump to ensure that negative air-pressure is not applied to the milk container.

The milk container forms the base of the system.

The milk container has a flat base so that it can rest stably on a surface.

The milk container is removable from the housing.

The milk container includes a clear or transparent wall or section to show the amount of milk collected.

The milk container is sealable for storage.

The milk container obviates the need for consumable or replaceable milk pouches.

The milk container includes an aperture that sits directly underneath an opening in a nipple tunnel of a breast shield, and expressed milk flows under gravity through the opening in the nipple tunnel and into the milk container through the pouring spout in the milk container.

The milk container is made using a blow moulding construction.

The milk container has a large diameter opening to facilitate cleaning that is at least 3 cm in diameter.

The large opening is closed with a bayonet-mounted cap with an integral spout.

D. Elvie IR System Feature Cluster

Feature 37 Elvie is wearable and includes a light-based system that measures the Quantity of Milk in the Container for Fast and Reliable Feedback

A system for milk volume determination, for use as part of a breast pump, or breast milk collecting device, including:

(a) a re-useable rigid or non-collapsible milk container;

(b) at least one light emitter, configured to direct radiation towards the surface of the milk;

(c) at least one light detector, configured to detect reflected radiation from the surface of the milk;

wherein the light emitters and detectors operate as part of a sub-system that measures the height of, or infers the quantity of, the milk in the container.

Optional:

The wearable breast pump system includes:

(a) a housing shaped at least in part to fit inside a bra and including a pumping mechanism;

(b) and a breast shield;

(c) a re-useable rigid or non-collapsible milk container that when connected to the housing is positioned to form the base of the housing;

and in which the top of the container includes an optically clear region that is aligned below one or more light emitters positioned in the base of the housing.

The sub-system measures or infers the quantity and/or the height of the liquid in the container by using one or more light emitters and light detectors to detect light from the emitters that has been reflected by the liquid, and measuring the intensity of that reflected light.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Where the quantity or level exceeds a threshold, then the pumping mechanism automatically changes mode, e.g. from a stimulation mode to an expression mode.

Where the quantity or level exceeds a threshold, then the pumping mechanism automatically stops.

Milk-flow data is captured and stored.

If milk-flow falls below a threshold, then a notification is provided to the mother.

Feature 38 the Separate IR Puck for Liquid Quantity Measurement

A liquid-level measuring system for measuring the quantity of liquid in a container for a breast pump; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to detect light from the light emitters that has been reflected from the liquid;

(c) a sub-system that infers, measures or calculates the quantity in the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

The quantity of milk is measured as milk enters the container or as milk is removed from the container.

Measured property includes the reflected light intensity

Feature 39 the Separate IR Puck Combined with Liquid Tilt Angle Measurement

A liquid-level measuring system for measuring the tilt angle of liquid in a container; the system including:

(a) one or more light emitters directing light at the surface of the liquid in the container;

(b) one or more light receivers configured to measure properties of the light reflected from the liquid;

(c) a sub-system including an accelerometer that infers, measures or calculates the tilt angle of the liquid using measured properties of the detected light;

(d) a collar or other fixing system that positions the system over the container.

Optional:

Measured property includes the reflected light intensity

The quantity of liquid is measured as liquid enters the container or as liquid is removed from the container.

Sub-system includes an accelerometer and uses a signal from the accelerometer to determine if the liquid is sufficiently still to permit the sub-system to accurately measure or infer the quantity and/or the height of the liquid in the container.

The sub-system measures or infers the quantity and/or the height of the liquid in the container and shares that data with a data connectivity module.

Generally Applicable Optional Features

Weight of the entire unit, unfilled, is under 250 g and preferably 214 g.

Silver based bactericide is used on all parts that are not steam or heat sterilized in normal cleaning.

Housing includes a rechargeable battery.

System is self-contained.

System is a closed loop system.

Breast pump system is a self-contained, wearable device that includes an integral rechargeable battery, control electronics, and one or more air pumps operating as a closed system, driving a flexible diaphragm that in turn delivers negative air-pressure to the breast, to cause milk to be expressed.

Housing has a generally rounded or convex front surface and has a generally tear-drop shape when seen from the front.

E. Bra Clip Feature Cluster

Feature 40 Bra Adjuster

A bra adjuster for a nursing or maternity bra, the nursing or maternity bra including a bra cup with a flap that can be undone to expose the nipple, and the flap attaching to the shoulder strap using a clasp, hook or other fastener attached to the flap, and a corresponding fastener attached to the shoulder strap;

and in which the bra adjuster is attachable at one end to the fastener attached to the flap, and at its other end to the fastener attached to the shoulder strap, and hence increases the effective bra cup size sufficiently to accommodate a wearable breast pump, and is also detachable from the flap and shoulder strap.

Optional:

Bra adjuster is retained in position on the bra during normal wearing of the bra, even when the flap is attached directly to the shoulder strap, and is used to increases the effective bra cup size only when the wearable breast pump is used.

Bra adjuster is extensible or elastic.

Bra adjuster is of a fixed length.

Bra adjuster includes a clip that the user can slide onto the bra strap to secure the bra adjuster in position.

Bra adjuster is machine-washing washable.

F. Other Features that can Sit Outside the Breast Pump Context

Feature 41 Wearable Device Using More than One Piezo Pump Connected in Series or in Parallel

A wearable device including multiple piezo pumps mounted together either in series or in parallel.

Optional:

The wearable device is a medical wearable device.

The piezo pumps air or any liquid etc.

The system can switch between a parallel mode and a series mode to arrive to lower or higher pressure quicker.

Feature 42 Wearable Medical Device Using a Piezo Pump and a Heat Sink Attached Together.

A wearable medical device including a piezo pump and a heat sink attached together.

Optional

- The wearable device uses more than one piezo pump connected in series.
- The wearable device uses more than one piezo pump connected in parallel.
- Each piezo pump is connected to its own heat sink, or to a common heat sink.
- The or each heat sink is configured to ensure that the maximum temperature of any parts of the breast pump system that might come into contact with the skin, especially prolonged contact for greater than 1 minute, are no more than 48° C. and preferably no more than 43° C.
- The wearable device includes a thermal cut out.
- Excess heat is diverted to a specific location on the device that is selected to not be in prolonged contact with the skin of the user, in normal use.
- Use cases application:
  - Wound therapy
  - High degree burns
  - Sleep apnea
  - Deep vein thrombosis
  - Sports injury.
- Wearable medical device is powered/charged via USB.

Note

It is to be understood that the above-referenced arrangements are only illustrative of the application for the principles of the present invention. Numerous modifications and alternative arrangements can be devised without departing from the spirit and scope of the present invention. While the present invention has been shown in the drawings and fully described above with particularity and detail in connection with what is presently deemed to be the most practical and preferred example(s) of the invention, it will be apparent to those of ordinary skill in the art that numerous modifications can be made without departing from the principles and concepts of the invention as set forth herein.

The invention claimed is:

1. A breast pump device comprising:

a self-contained, in-bra wearable device comprising:

a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge;

a housing that includes:

a battery, and

the air pump powered by the battery and configured to generate negative air pressure by driving the diaphragm;

a breast shield comprising a breast flange and a nipple tunnel extending from the breast flange, the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and the breast shield being separate from the diaphragm; and

a milk container that is configured to attach to the housing and receive expressed milk via the milk port.

2. The breast pump device of claim **1**, wherein the breast shield is configured to rotate smoothly around a nipple inserted into the nipple tunnel to provide a correct positioning of the breast shield onto a breast.

3. The breast pump device of claim **1**, wherein the breast shield is a one-piece item that, in use, presents a single continuous surface to a nipple and a breast.

4. The breast pump device of claim **1**, wherein the breast shield integrates the breast flange and nipple tunnel as a one-piece item.

5. The breast pump device of claim **1**, wherein the breast flange and the nipple tunnel are a single, integral item with no joining stubs.

6. The breast pump device of claim **1**, wherein the breast shield is generally symmetrical about a centre-line running from a top to a bottom of the breast shield when positioned upright for normal use.

7. The breast pump device of claim **1**, wherein the breast shield is configured to slide in and out from the housing, together with the diaphragm, on guide members in the breast shield.

8. The breast pump device of claim **1**, wherein the housing is configured to slide onto the breast shield, when the breast shield has been placed onto a breast, using guide members.

9. The breast pump device of claim **1**, wherein the breast pump device includes only the breast shield and the milk container that are directly removable from the housing in normal use or normal dis-assembly.

10. The breast pump device of claim **1**, wherein the diaphragm is substantially circular and is configured to self-seal under the negative air pressure to a substantially circular diaphragm holder that is part of the housing.

11. The breast pump device of claim **1**, wherein the diaphragm is a membrane, and the diaphragm deforms in response to changes in air pressure caused by the air pump to create negative air pressure in the nipple tunnel.

12. The breast pump device of claim **1**, wherein the diaphragm is removable from a diaphragm holder that sits above the breast flange and the nipple tunnel.

13. The breast pump device of claim **1**, wherein the milk container is substantially rigid.

14. The breast pump device of claim **1**, wherein the milk container is configured to attach to a lower part of the housing and to form a flat bottomed base for the breast pump device.

15. The breast pump device of claim **1**, wherein the milk container has a surface shaped to continue a curved shape of the housing, so that the breast pump device can be held comfortably inside the bra.

16. The breast pump device of claim **1**, wherein the milk container includes a flexible valve that self-seals under negative air pressure against the milk port in the nipple tunnel and that permits the expressed milk to flow into the milk container.

17. The breast pump device of claim **1**, wherein the milk container is attachable to the housing with a mechanical or magnetic mechanism that releasably attaches or latches when the milk container is sufficiently pressed on to the housing with a single push action.

18. The breast pump device of claim **1**, wherein the milk container includes a cap that is removable from the milk container and a removable valve that enables milk to pass into the milk container in one direction.

19. The breast pump device of claim **1**, wherein a top of the milk container includes an optically clear region that is aligned below one or more light emitters positioned in a base of the housing.

20. The breast pump device of claim **1**, wherein the milk container is wider than the milk container is tall.

21. The breast pump device of claim **1**, wherein the nipple tunnel includes on a lower surface the milk port through which the expressed milk flows under gravity into the milk container.

22. The breast pump device of claim **1**, wherein the housing includes a wireless data communication system powered by the battery.

23. The breast pump device of claim **1**, wherein the housing has a front surface that is configured to fit inside a bra and to contact an inner surface of the bra, and a rear surface that is shaped to contact, at least in part, the breast shield.

24. The breast pump device of claim **1**, wherein the housing includes at least one of a visual or haptic indicator that indicates whether milk is flowing or not flowing into the milk container.

25. The breast pump device of claim **1**, wherein the housing includes at least one of a visual or haptic indicator that indicates if the air pump is operating correctly to pump milk, based on whether a quantity or a height of liquid in the milk container above a base of the milk container is increasing above a threshold rate of increase.

26. The breast pump device of claim **1**, wherein the air pump comprises a piezo air pump system.

27. The breast pump device of claim **1**, wherein a total mass of the breast pump device, unfilled with milk, is less than 250 gm.

28. The breast pump device of claim **1**, wherein the breast pump device makes less than 30 dB noise at maximum power and less than 25 dB at normal power, against a 20 dB ambient noise.

29. The breast pump device of claim **1**, wherein the air pump is configured to generate negative air pressure with a maximum suction of approximately 240 mmHg.

* * * * *

Exhibit 27

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S9**
Claim 1		
1.P	A breast pump device comprising:	The Momcozy S9 is a breast pump device. The Momcozy S9 is described as a “2 Mode Wearable Electric Breast Pump.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

<table>
<tr><th colspan="3">The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9</th></tr>
<tr><td>1.1</td><td>a self-contained, in-bra wearable device comprising:

a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge;</td><td>The Momcozy S9 is a breast pump device that is configured as a self-contained device, as shown below.


The Momcozy S9 is an in-bra wearable device.</td></tr>
</table>

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

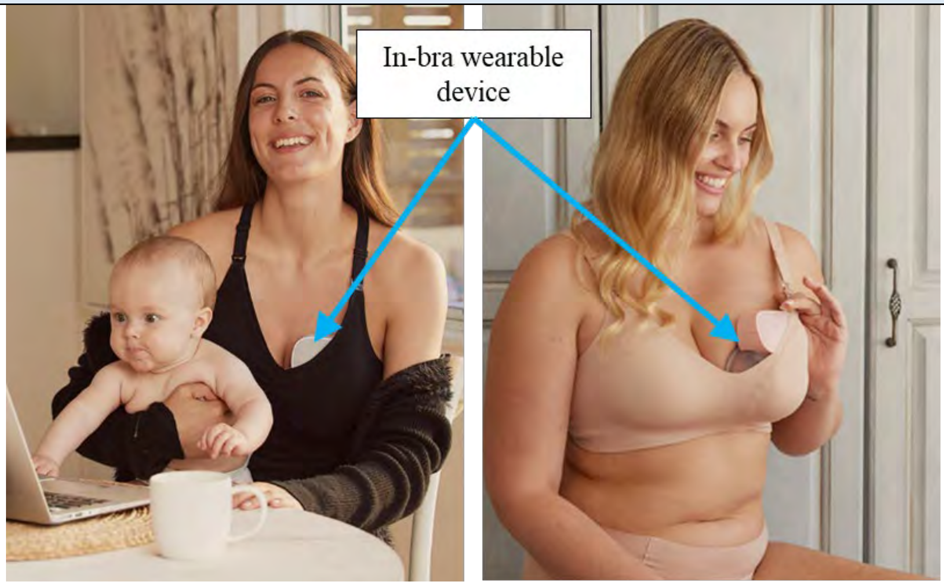
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
	Claim Language	**Momcozy S9**
		 (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) As shown above, the Momcozy S9 is in-bra wearable. The Momcozy website explains that the Momcozy S9 is described as “Wearable, Fit Inside Bras.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) The Momcozy S9 “pump is able to fit inside normal nursing bras for the whole day to get rid of ‘finding nursing room’ and ‘repeated bra-offs’ games.” (*Id.*) The Momcozy S9 includes a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge. The Momcozy website states that the Momcozy S9 product includes a “silicone diaphragm.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9, under “What’s included” tab.)

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

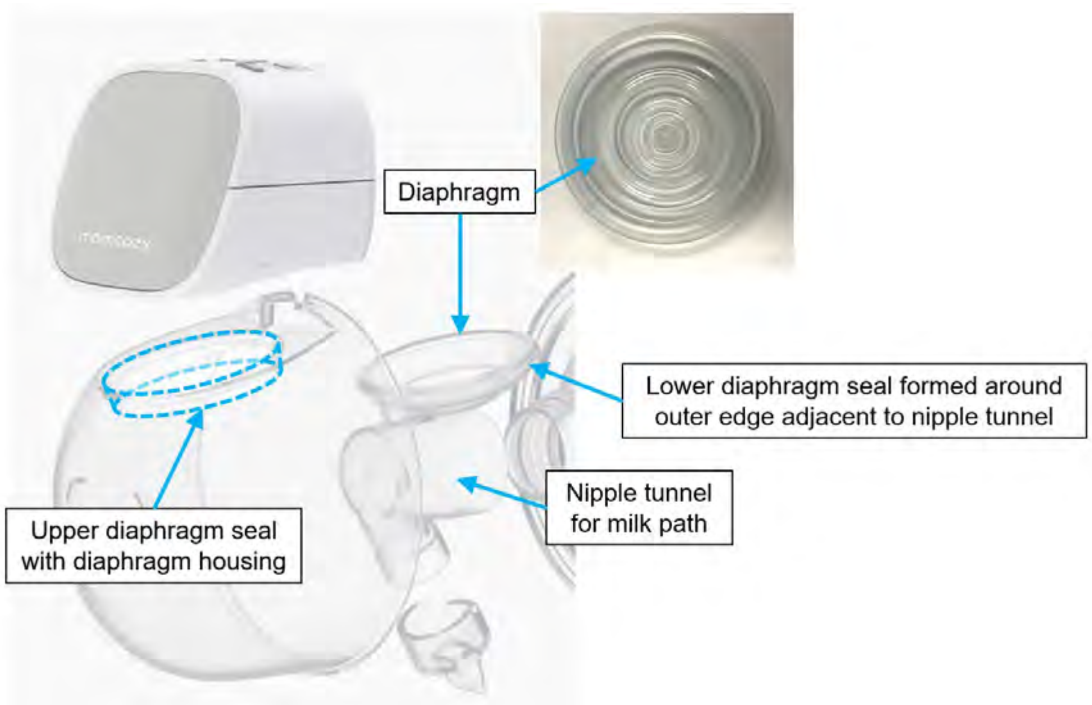
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9**
		The diaphragm has an outer edge that seals on a lower side to a housing adjacent to the nipple tunnel, and seals on an upper side with a diaphragm housing.  When milk is expressed through the nipple tunnel, the diaphragm prevents milk from reaching the pump as shown below.

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

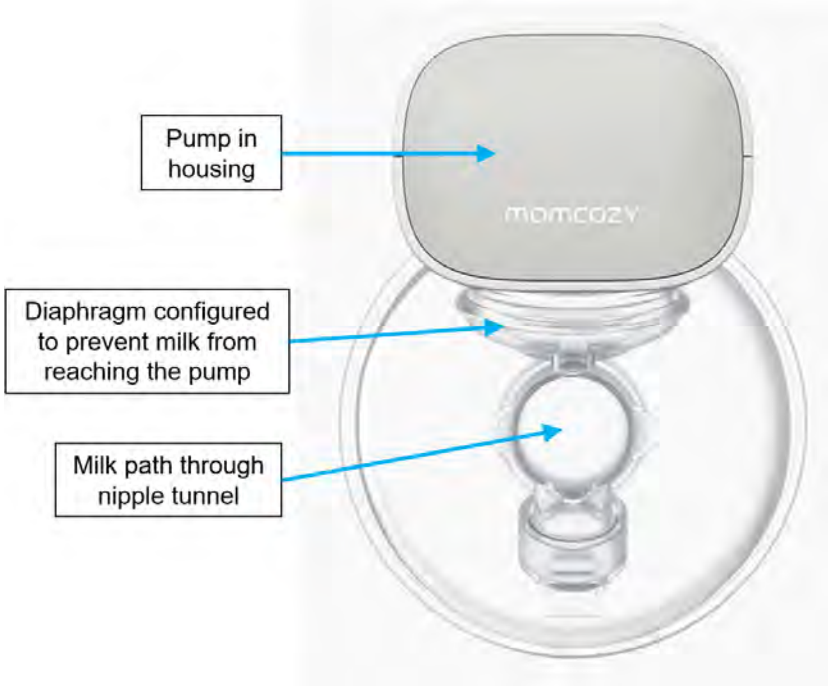
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S9**
		

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

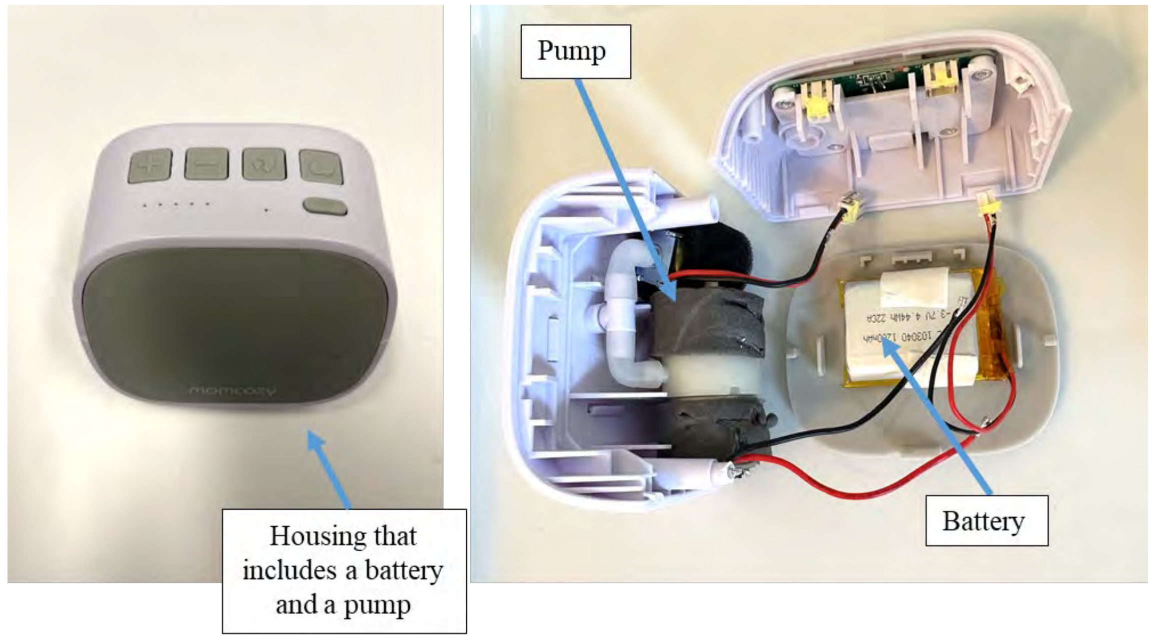
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S9**
1.2	a housing that includes: a battery, and the air pump powered by the battery and configured to generate negative air pressure by driving the diaphragm;	The Momcozy S9 includes a housing that includes a battery and an air pump powered by the battery and is configured to generate negative air pressure by driving the diaphragm.  The Momcozy S9 housing includes a battery. For example, the Momcozy S9 user guide states that “[t]his product has a built-in battery,” and that they “recommend that you use a certified 5V==1A adapter to charge the battery.” (Momcozy, S9 User Manual, p. 2.) The Momcozy S9 housing includes a pump powered by the battery and generates negative air pressure. For example, the Momcozy website advertises that the “wearable hands-free pump can be worn inside a standard nursing bra, so you can pump completely hands-free anytime, anywhere.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

<table>
<tr><th colspan="3">The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9</th></tr>
<tr><td></td><td></td><td>
The Momcozy S9 user guide also identifies the housing as the “pump motor,” as shown as item 4 in the figure below. (Momcozy, S9 User Manual, p. 1.)

The Momcozy S9 pump generates negative air pressure. For example, the Momcozy website states that the S9 breast pump has “5 Adjustable ***Suction*** Levels.” (*Id.*, under “Feature” tab (emphasis added).)

The Momcozy S9 pump drives the diaphragm to create negative air pressure.
</td></tr>
</table>

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S9**
		The Momcozy S9 includes the diaphragm which deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. The Momcozy S9 product is advertised as having “5 Adjustable Suction Levels and 2 Modes.” (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) On information and belief, when the pump is operated in the housing, it creates a change in air pressure that deforms the diaphragm to create negative pressure in the nipple tunnel. 
1.3	a breast shield comprising a breast flange and a nipple	The Momcozy S9 also includes a breast shield with a breast flange and a nipple tunnel that extends from the breast flange.

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

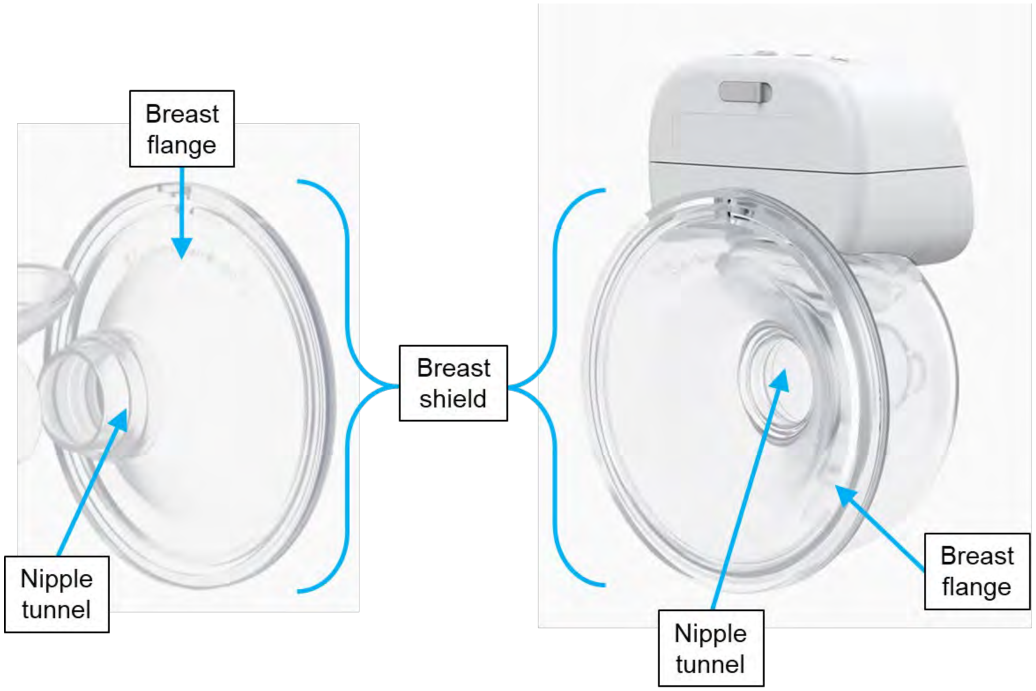
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9**
	tunnel extending from the breast flange, the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and the breast shield being separate from the diaphragm; and	For example, the Momcozy S9 includes a "Silicone Shield (24 mm)." (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.)  (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) The nipple tunnel comprises a closed end and a milk port intermediate to the breast flange and the closed end.

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

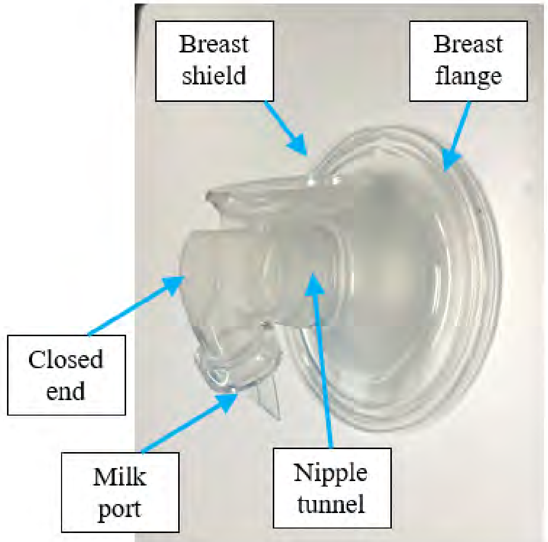
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S9**
		 The Momcozy S9 includes a breast shield that is separate from the diaphragm.

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

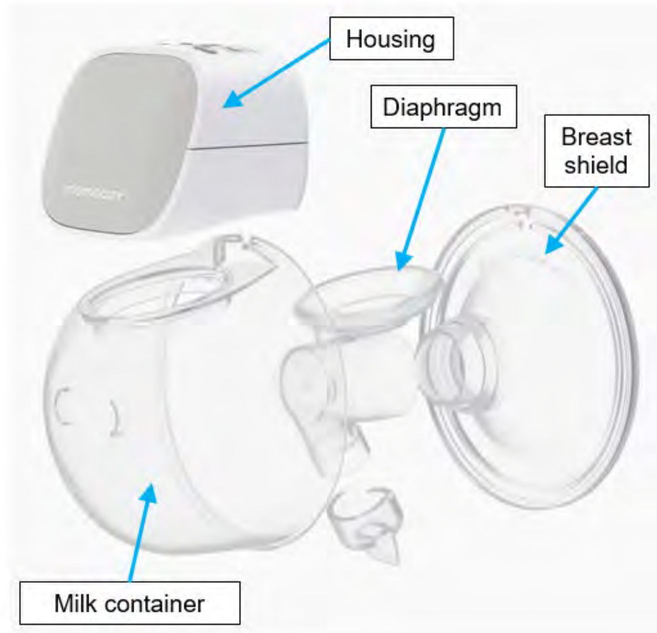
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S9**
		
1.4	a milk container that is configured to attach to the housing and receive expressed milk via the milk port.	The Momcozy S9 includes a milk container that is configured to attach to the housing and receive expressed milk via the milk port. The Momcozy S9 includes a milk container.

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9**
		 The Momcozy website shows that the S9 product includes a "milk collector (180ml/6oz)." (https://momcozy.com/products/double-electric-wearable-breast-pump-s9.) The Momcozy S9 milk container is configured to be attached to the housing.

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S9**
		 The S9 user guide illustrates attachment of the housing to the milk container, as shown below. (Momcozy, S9 User Manual, p. 10.)

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

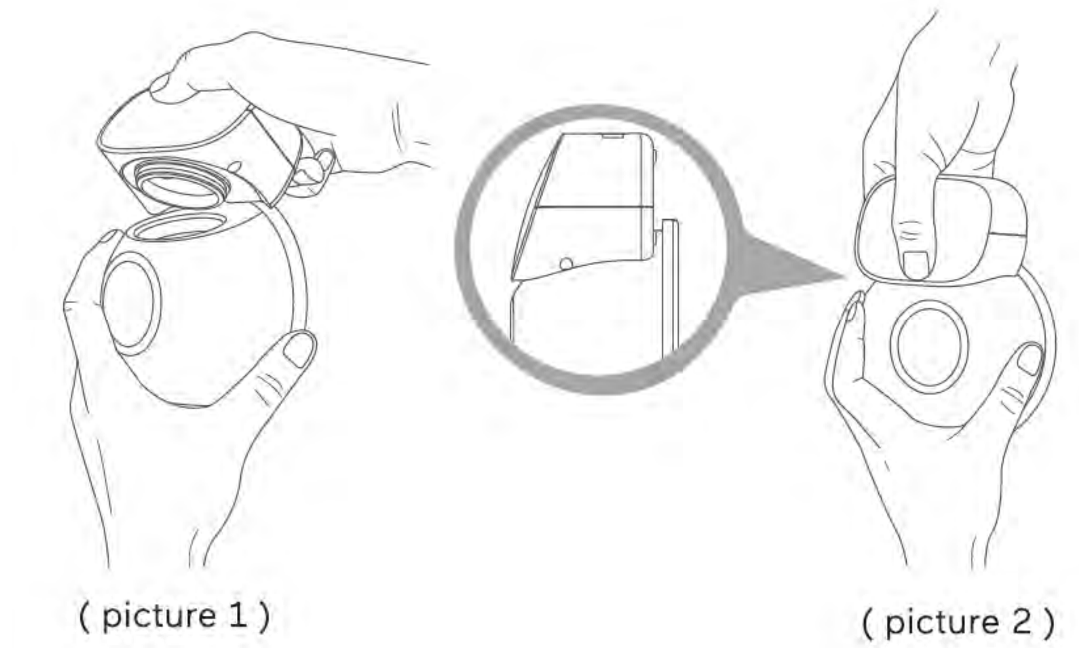
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9**
		 The Momcozy S9's milk container receives milk through the milk port that is located inside of the milk container.

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
	Claim Language	**Momcozy S9**
		 The Momcozy User Manual directs users to place the milk port into the milk container as shown below (Momcozy, S9 User Manual, p. 4.)

Exhibit 27 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Product

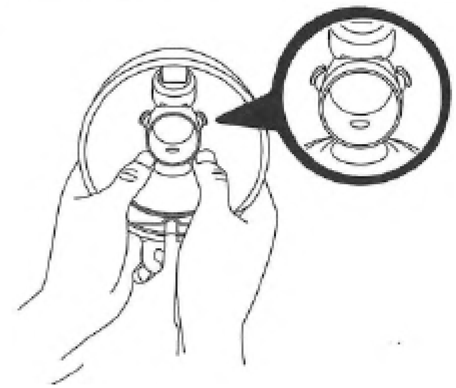
The Momcozy S9 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9**
		3. Put the assembled linker into the Milk Collector, with the "ear" part of the Linker aligned with the internal slot of the Milk Collector and press the Linker disc part with both hands to fasten the edges firmly to ensure complete sealing. 

Exhibit 28

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

<table>
<tr><th colspan="3">The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S9 Pro</th></tr>
<tr><td colspan="3">Claim 1</td></tr>
<tr><td>1.P</td><td>A breast pump device comprising:</td><td>The Momcozy S9 Pro is a breast pump device. The Momcozy S9 Pro is described as the “S9 Pro Wearable Breast Pump.” (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)</td></tr>
<tr><td>1.1</td><td>a self-contained, in-bra wearable device comprising:

a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge;</td><td>The Momcozy S9 Pro is a breast pump device that is configured as a self-contained device.
</td></tr>
</table>

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9 Pro**
		The Momcozy S9 Pro is an in-bra wearable device. The Momcozy website states that the Momcozy S9 Pro "is designed to be worn with your standard nursing bra." (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)  (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

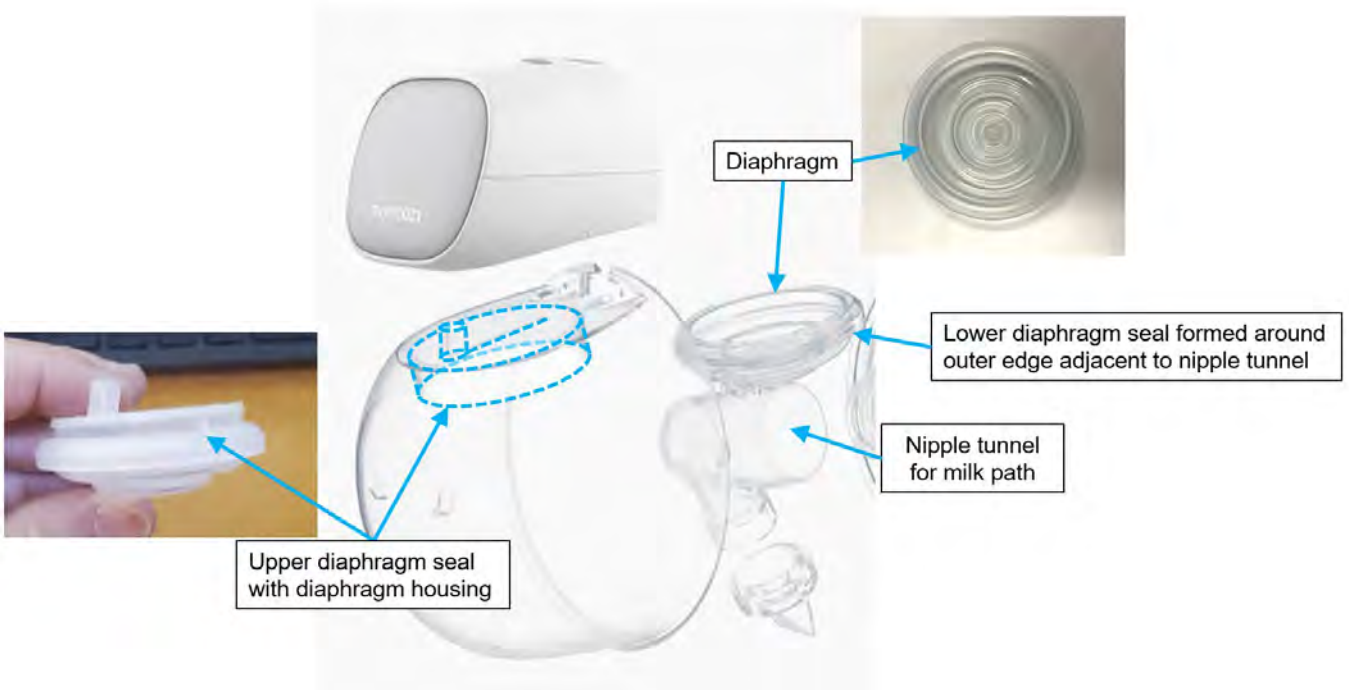
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.	
Claim Language	**Momcozy S9 Pro**
	The Momcozy S9 Pro includes a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge. The Momcozy website indicates that the S9 Pro product includes a "Silicone Diaphragm." (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.) The diaphragm has an outer edge that seals on a lower side to a housing adjacent to the nipple tunnel, and seals on an upper side with a diaphragm housing.  When milk is expressed through the nipple tunnel, the diaphragm prevents milk from reaching the pump as illustratively shown below.

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

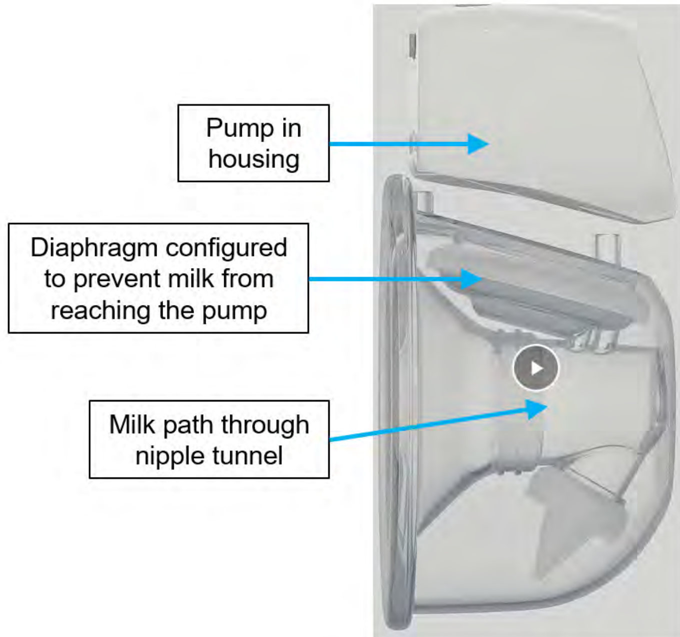
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9 Pro**
		 When the pump is fully assembled, the diaphragm fits into the diaphragm holder, and the outer edge of the diaphragm creates a seal to prevent the milk from entering the air pump.

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

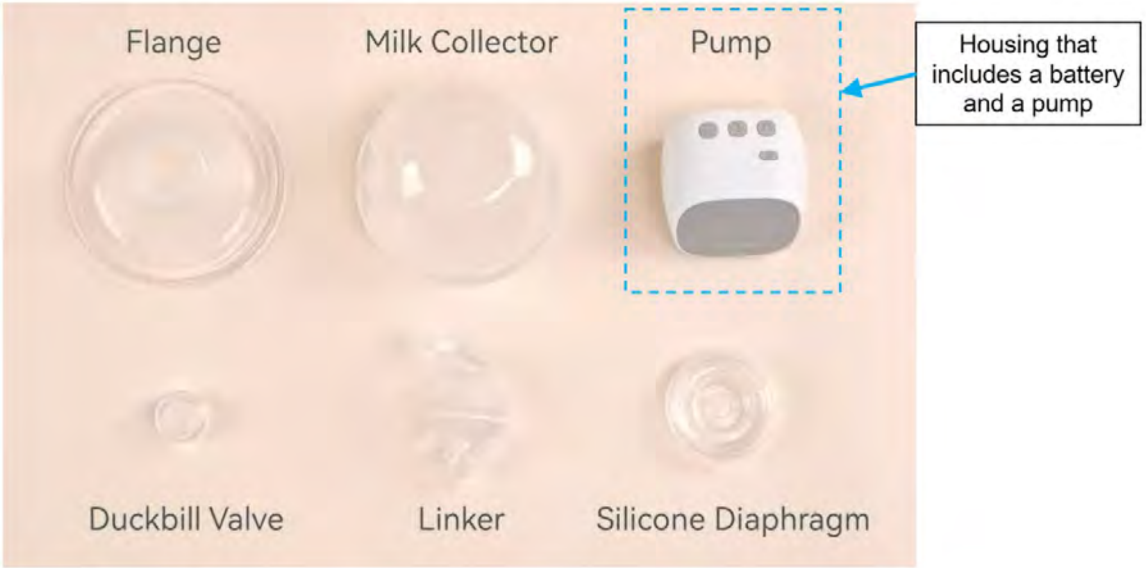
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9 Pro**
1.2	a housing that includes: a battery, and the air pump powered by the battery and configured to generate negative air pressure by driving the diaphragm;	The Momcozy S9 Pro includes a housing that includes a battery and an air pump.  Still image from Momcozy S9 Pro video (https://www.amazon.com/Momcozy-S9-Pro-Wearable-Hands-Free/dp/B0B74TFJCF?th=1.) The Momcozy S9 Pro housing includes a battery. For example, the Momcozy S9 Pro user guide provides details on charging the battery. (Momcozy S9 Pro User Guide, p. 13.) The Momcozy website describes the Momcozy S9 Pro as having a "Long Battery Life." (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

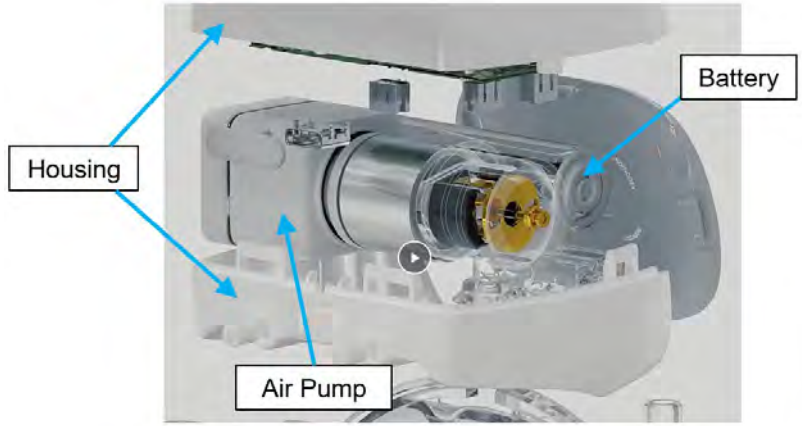
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9 Pro**
		 Still image from Momcozy S9 Pro video (https://www.amazon.com/Momcozy-S9-Pro-Wearable-Hands-Free/dp/B0B74TFJCF) The Momcozy S9 Pro housing includes an air pump powered by the battery that generates negative air pressure. The Momcozy website advertises that the Momcozy S9 Pro includes a "Pump motor" and that the "S9 Pro hands-free pumps in a better efficiency with less time, saving more time for moms." (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump?variant=42680176738502.) The Momcozy website describes the Momcozy S9 Pro as having "Hospital grade 280 ~ 300mmHg suction range." (*Id.*) The Momcozy S9 Pro pump generates negative air pressure. For example, the Momcozy website states that the Momcozy S9 Pro breast pump "owns 2 modes of expression and mixed suction with 9 intensity levels for each." (*Id.*) The Momcozy S9 Pro user guide also states that the "Momcozy pump has 9 vacuum pressure settings for each mode, giving you control over what feels comfortable and works most efficiently in both stimulation and expression modes." (Momcozy S9 Pro User Guide, p. 12.)

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

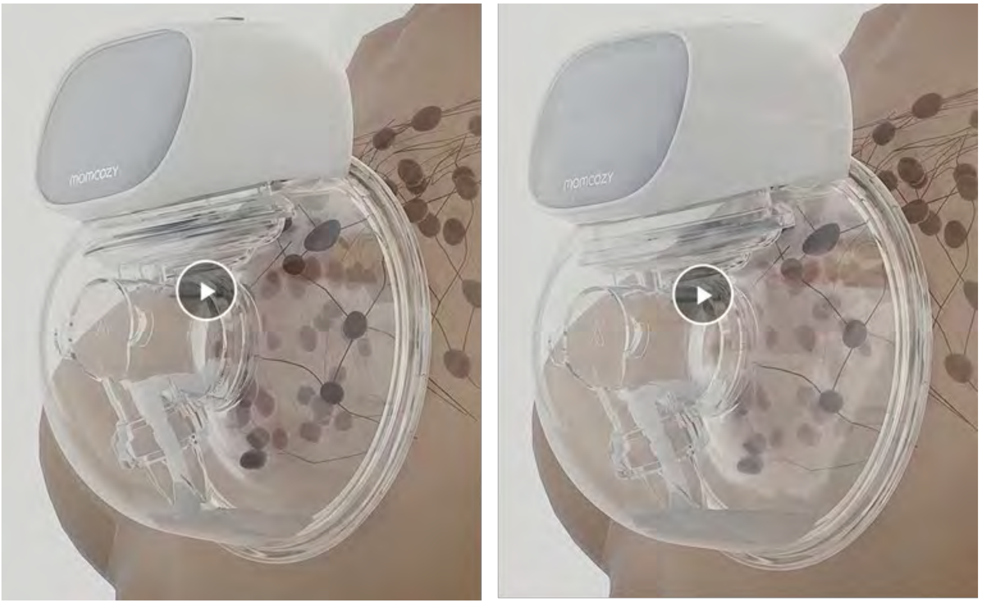
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.	
Claim Language	**Momcozy S9 Pro**
	The Momcozy S9 Pro includes the diaphragm that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. The Momcozy S9 Pro user guide states that the “Momcozy pump has 9 vacuum pressure settings for each mode.” (Momcozy S9 Pro User Guide, p. 12.) As shown in the images below, the diaphragm deforms to create negative air pressure in the nipple tunnel.  (https://www.youtube.com/watch?v=MUlexBZCbPU&list=TLGGtd591n3S7cwMTAyMjAyNA&t=9s.)

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

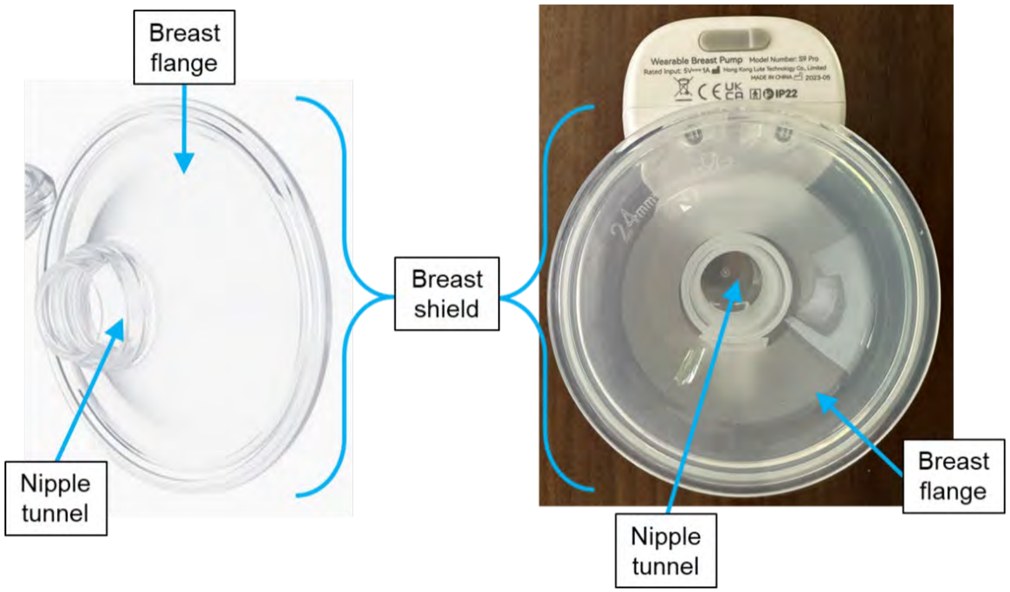
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9 Pro**
1.3	a breast shield comprising a breast flange and a nipple tunnel extending from the breast flange, the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and the breast shield being separate from the diaphragm; and	The Momcozy S9 Pro includes a breast shield made up of a breast flange and a nipple tunnel.  The Momcozy website states that the Momcozy S9 Pro includes a "Default Flange Size: 24mm." (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.) As shown above, the breast shield includes a breast flange and a nipple tunnel. The Momcozy S9 Pro's nipple tunnel is comprised of a closed end and a milk port intermediate to the breast flange and the closed end.

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

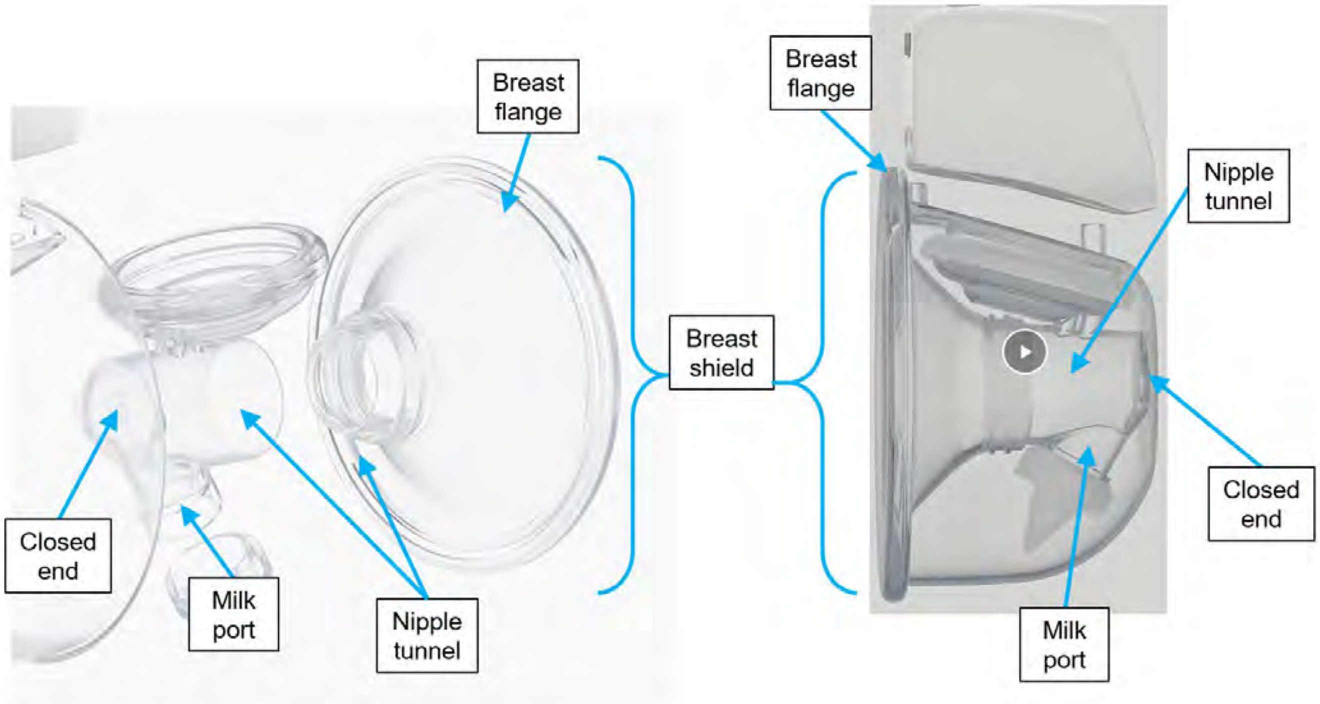
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9 Pro**
		 The Momcozy S9 Pro's breast shield is separate from the diaphragm.

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

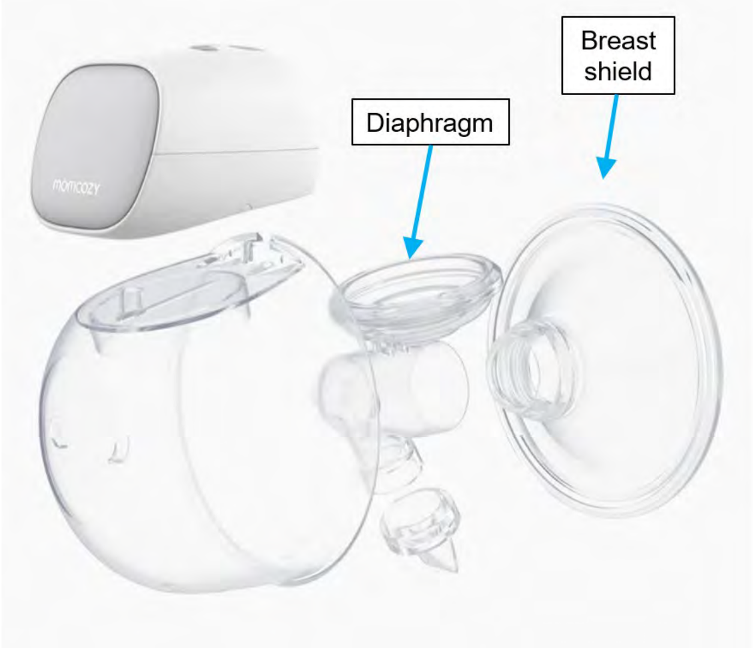
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S9 Pro**
		
1.4	a milk container that is configured to attach to the housing and receive expressed milk via the milk port.	The Momcozy S9 Pro includes a milk container that is configured to attach to the housing and receive expressed milk via the milk port. The Momcozy S9 Pro includes a milk container. The Momcozy website states that the Momcozy S9 Pro includes a "Milk Collector (180ml)." (https://momcozy.com/products/momcozy-s9-pro-wearable-breast-pump.)

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S9 Pro**
		

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

		The Momcozy S9 Pro milk container is configured to be attached to the housing.  The Momcozy S9 Pro's milk container receives milk through the milk port which is located inside the milk container.

Exhibit 28 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy S9 Pro Product

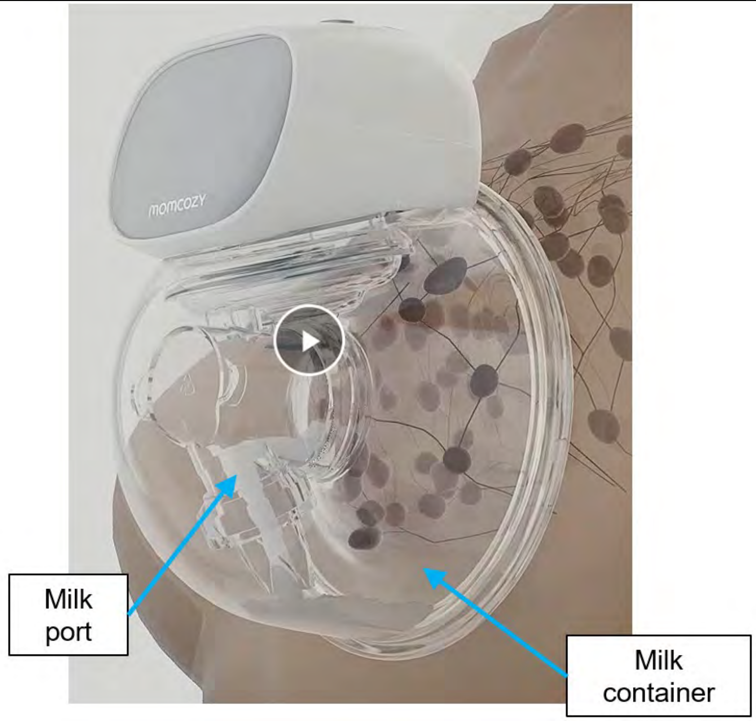
The Momcozy S9 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
	Claim Language	**Momcozy S9 Pro**
		 (https://www.youtube.com/watch?v=MUlexBZCbPU&list=TLGGGtd591n3S7cwMTAyMjAyNA&t=9s.)

Exhibit 29

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12**
Claim 1		
1.P	A breast pump device comprising:	The Momcozy S12 is a breast pump device. The Momcozy S12 is described as “9 Levels Wearable Electric Breast Pump - S12.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)
1.1	a self-contained, in-bra wearable device comprising: a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge;	The Momcozy S12 is a breast pump device that is configured as a self-contained device, as shown below.

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S12**
		 The Momcozy S12 is an in-bra wearable device.

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12**
		 (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The Momcozy S12 is described as a “Wearable Breast Pump.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The Momcozy S12 can “[f]it for any standard nursing bra.” (*Id.*) The Momcozy S12 includes a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge. The Momcozy website indicates that the S12 product includes a “silicone diaphragm.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The diaphragm has an outer edge that seals on a lower side to a housing adjacent to the nipple tunnel, and seals on an upper side with a diaphragm housing.

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

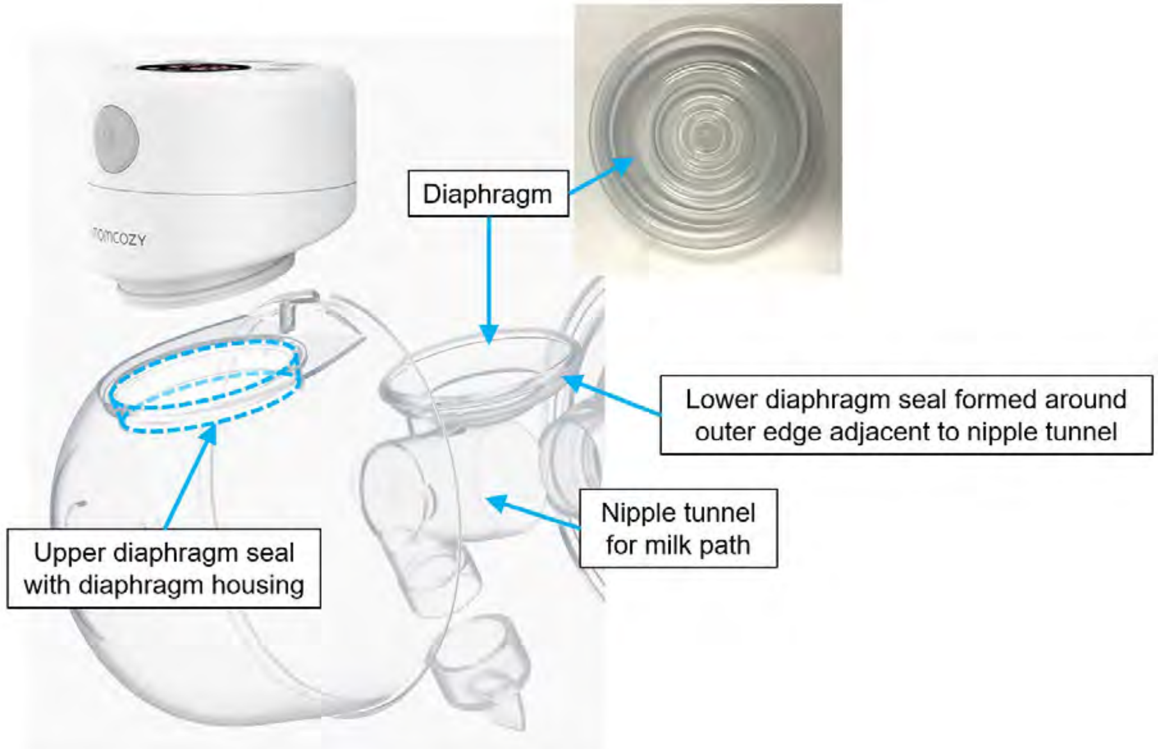
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S12**
		 When milk is expressed through the nipple tunnel, the diaphragm prevents milk from reaching the pump as illustratively shown below.

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

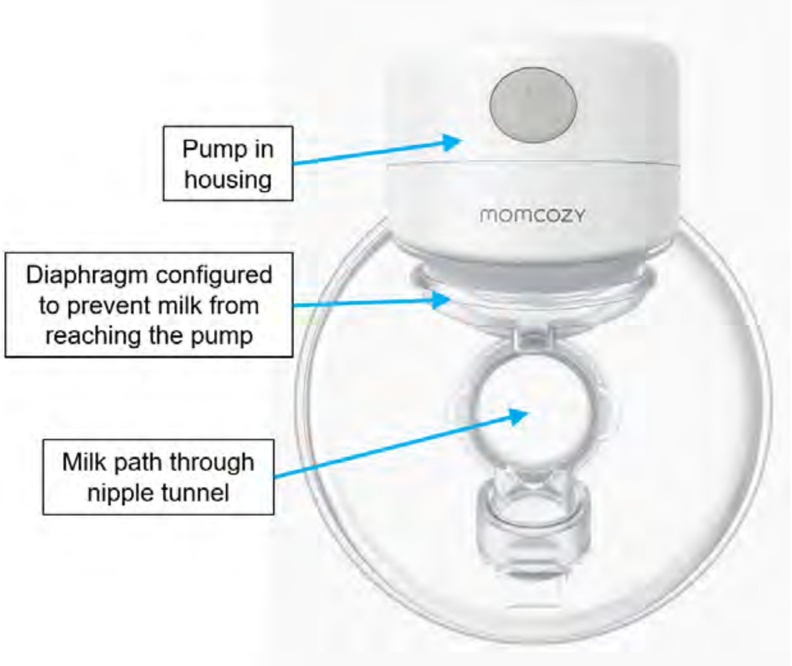
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12**
		

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

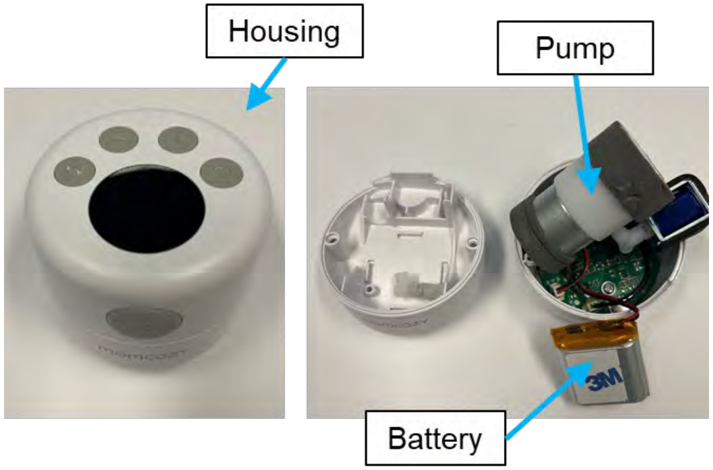
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12**
1.2	a housing that includes: a battery, and the air pump powered by the battery and configured to generate negative air pressure by driving the diaphragm;	The Momcozy S12 includes a housing that includes a battery and an air pump powered by the battery and is configured to generate negative air pressure by driving the diaphragm. The Momcozy S12 includes a housing, as shown below.  The Momcozy S12 pump housing includes a battery. For example, the Momcozy S12 user guide also states that “[t]his product has a built-in battery,” and that they “recommend that you use a certified 5V==1A adapter to charge the Pump Motor.” (Momcozy, S12 User Manual, p. 2.) The Momcozy website states that the Momcozy S12 is “[c]hargeable.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) On information and belief, the Momcozy S12 pump housing includes a power charging circuit for controlling the charging of the rechargeable battery and control electronics powered by the rechargeable battery because the Momcozy S12 is rechargeable and has buttons that change the operation of the pump. (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12**
		The Momcozy website advertises that “[t]his [S12] hands-free pump can be placed in the nursing bra so that you can pump milk anytime and anywhere. The wearable breastfeeding pump gives you the freedom to multitask during milk pumping.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The website also states that the S12 breast pump has “9 Adjustable **Suction** Levels.” (*Id.*) The Momcozy S12 pump drives the diaphragm to create negative air pressure. The Momcozy S12 includes a diaphragm that deforms in response to changes in air pressure caused by the pump to create negative air pressure in the nipple tunnel. The Momcozy S12 product is advertised as having “9 adjustable suction levels and 2 modes.” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) On information and belief, when the pump is operated in the housing, it creates a change in air pressure that deforms the diaphragm to create negative pressure in the nipple tunnel.

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

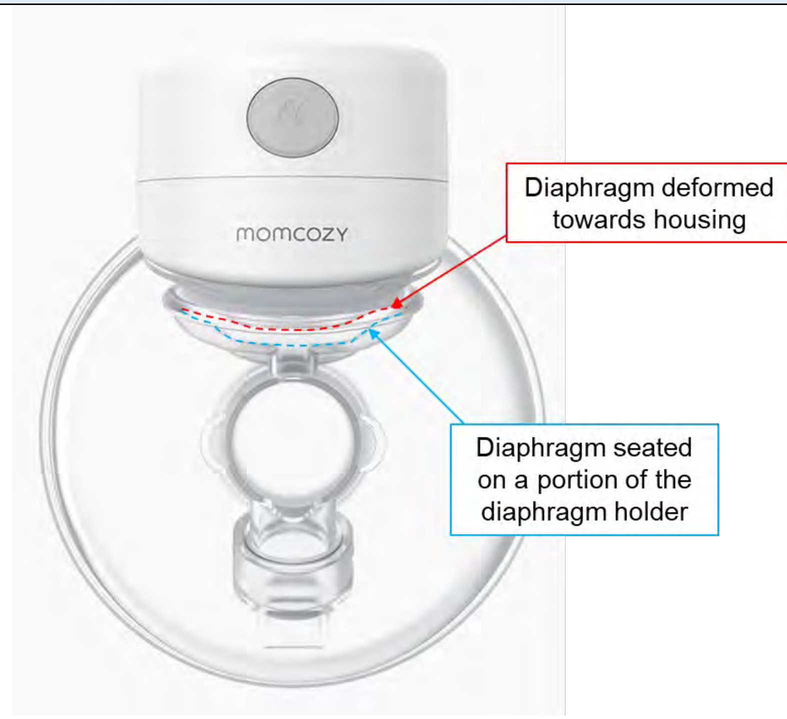
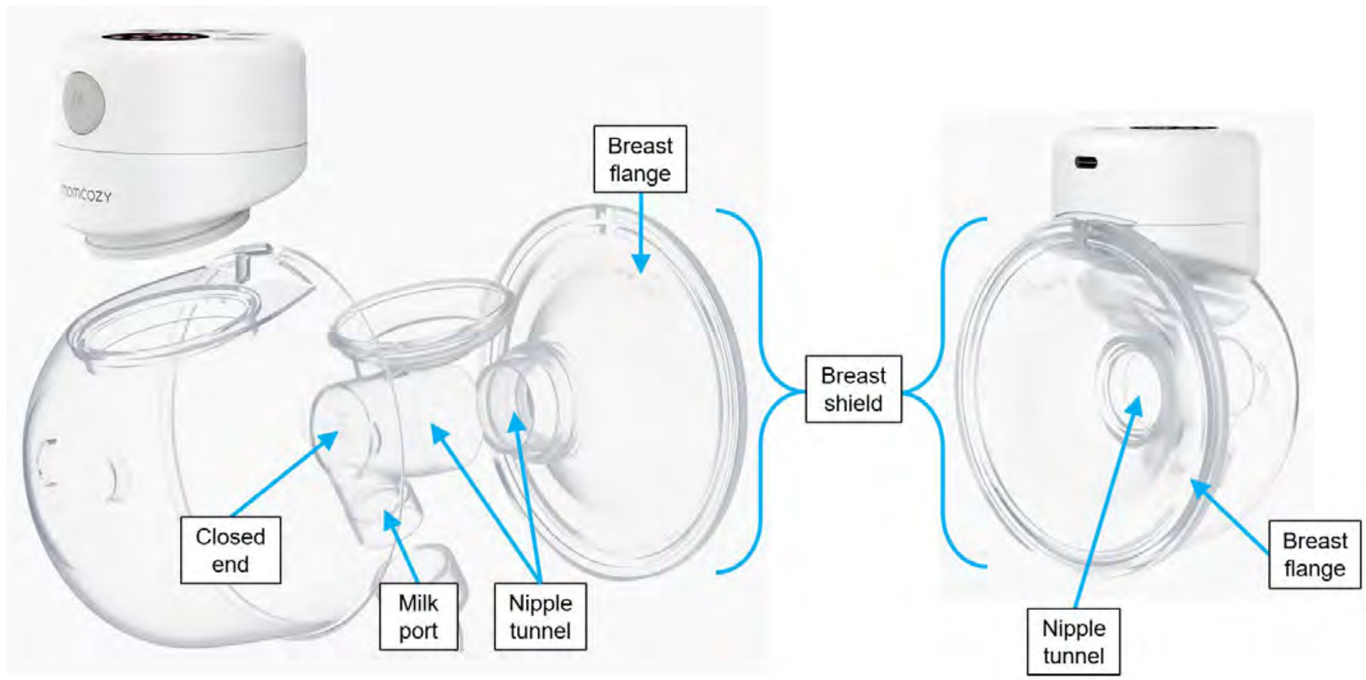
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.	
Claim Language	**Momcozy S12**
	

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

<table>
<tr><th colspan="3">The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12</th></tr>
<tr><td>1.3</td><td>a breast shield comprising a breast flange and a nipple tunnel extending from the breast flange, the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and the breast shield being separate from the diaphragm; and</td><td>The Momcozy S12 contains a breast shield comprised of a breast flange and a nipple tunnel extending from the breast flange.


(https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

The nipple tunnel comprises of a closed end and a milk port intermediate to the breast flange and the closed end.</td></tr>
</table>

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

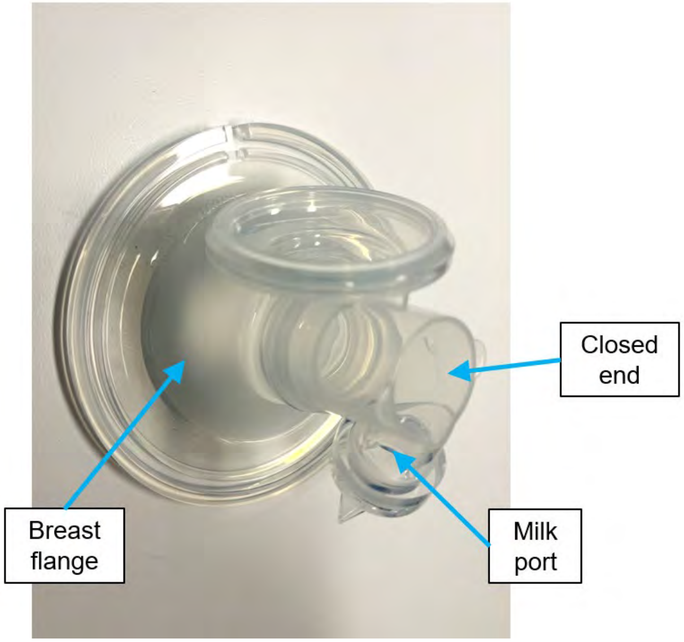
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12**
		 The Momcozy S12 includes a breast shield that is separate from the diaphragm.

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

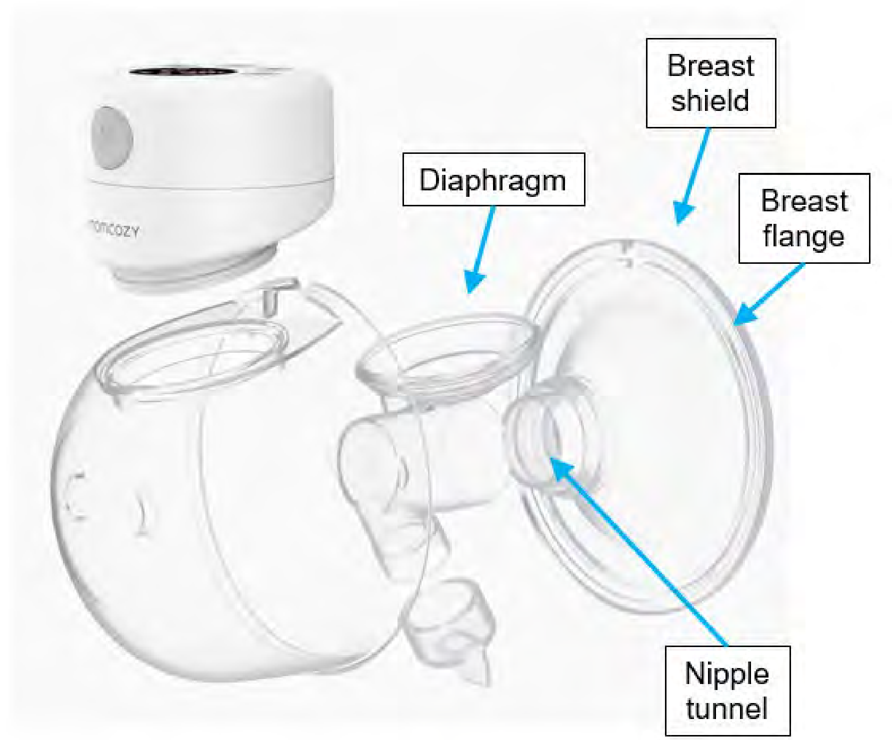
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12**
		
1.4	a milk container that is configured to attach to the housing and receive expressed milk via the milk port.	The Momcozy S12 includes a milk container that is configured to be attached to the housing. The Momcozy website clarifies that the S12 product includes a “milk collector (180ml/6oz).” (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.)

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12**
		 (https://www.youtube.com/watch?v=gQ0N_oNCJs0 at 0:24.)

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
	Claim Language	**Momcozy S12**
		 (https://momcozy.com/products/9-levels-double-wearable-breast-pump-s12.) The S12 user guide also illustrates the attachment of the housing to the milk container, as shown below. (Momcozy, S12 User Manual, p. 10.)

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

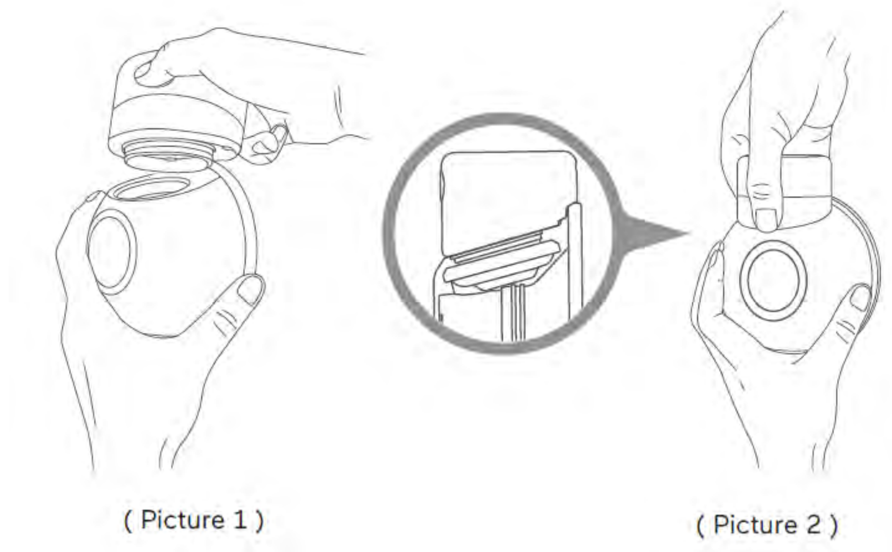
The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S12**
		 The Momcozy S12 milk container receives milk through the milk port which, when fully assembled, is located inside the milk container.

Exhibit 29 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Product

The Momcozy S12 includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		Momcozy S12
		

Exhibit 30

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S12 Pro**
Claim 1		
1.P	A breast pump device comprising:	The Momcozy S12 Pro is a breast pump device. The Momcozy website states that the Momcozy S12 Pro is a "Wearable Breast Pump." (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.)
1.1	a self-contained, in-bra wearable device comprising: a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge;	The Momcozy S12 Pro is a breast pump device that is configured as a self-contained device, as shown below. 

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12 Pro**
		The Momcozy S12 Pro is an in-bra wearable device.  (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.) The website states that “this bra-fit wearable breast pump allows for ultimate free pumping on the go for multitasking and body motion to exercise, which is a shortcut for moms to get the balance of nursing babies and regain normal lives.” (*Id*.) Additionally, the Momcozy website discloses that “[Momcozy’s] hands-free breast pump is designed to be worn with your standard nursing bra.” (*Id*.) The Momcozy S12 Pro includes a diaphragm configured to prevent milk from reaching an air pump by forming a seal around its outer edge. The Momcozy website clarifies that the S12 Pro product includes a “silicone diaphragm.” (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump?variant=42641714741446)

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

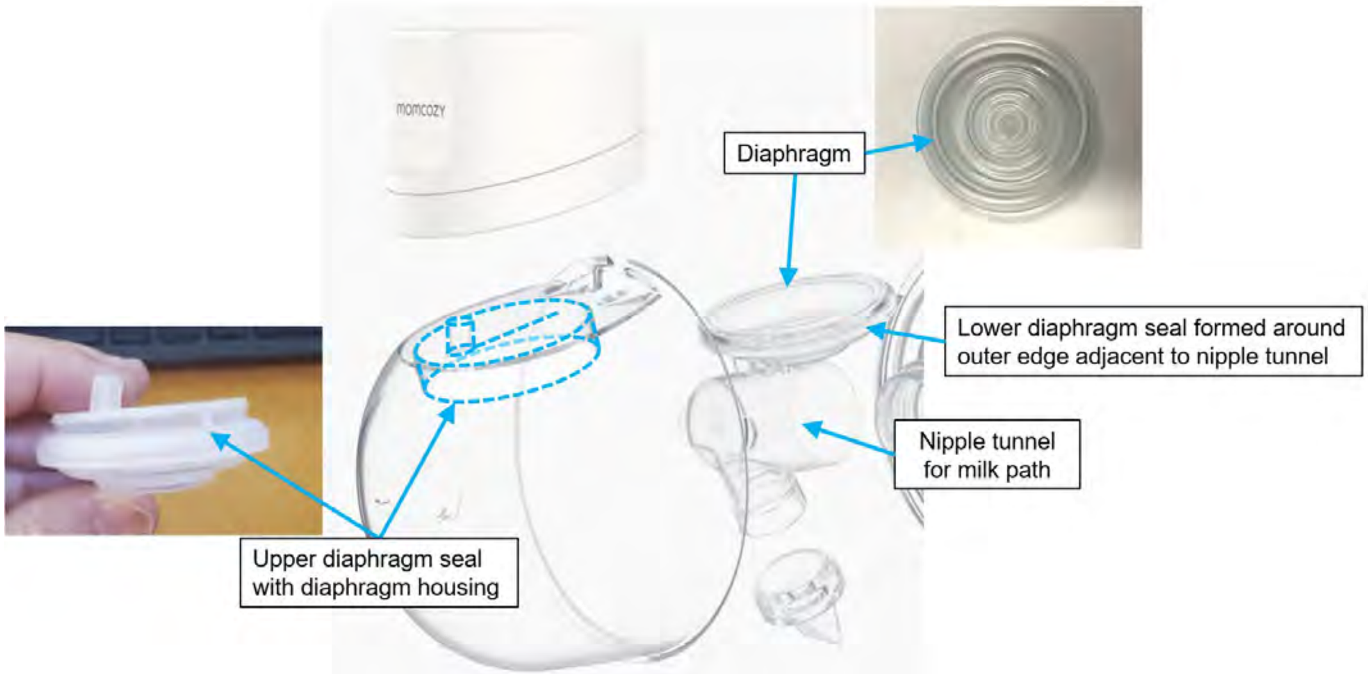
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12 Pro**
		The diaphragm has an outer edge that seals on a lower side to a housing adjacent to the nipple tunnel, and seals on an upper side with a diaphragm housing.  When milk is expressed through the nipple tunnel, the diaphragm prevents milk from reaching the pump as illustratively shown in the Momcozy advertising material below.

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

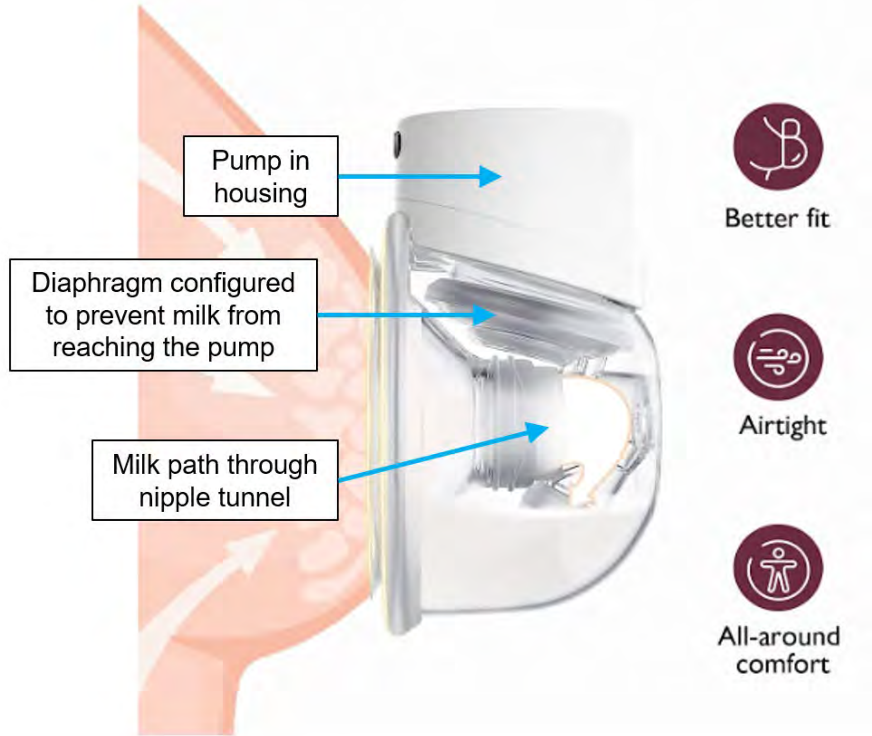
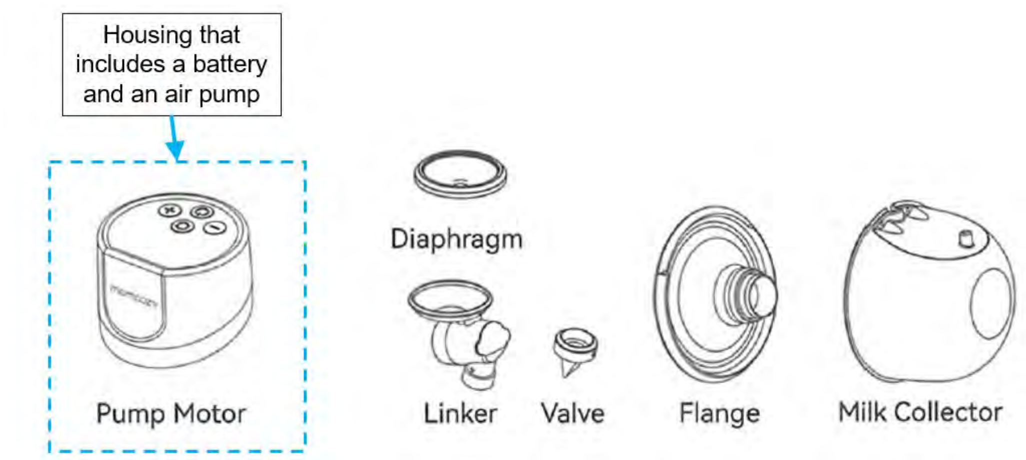
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S12 Pro**
		 Momcozy advertising material showing diaphragm preventing milk from reaching the pump housed in the housing. When the pump is fully assembled, the diaphragm fits into the diaphragm holder, and the outer edge of the diaphragm creates a seal to prevent the milk from entering the air pump.

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td>1.2</td><td>a housing that includes:

a battery, and

the air pump powered by the battery and configured to generate negative air pressure by driving the diaphragm;</td><td>The Momcozy S12 Pro includes a housing that includes a battery and an air pump.



Momcozy S12 Pro Quick guide, p. 2

The Momcozy S12 Pro housing includes a battery. For example, the Momcozy S12 Pro user guide states that “[w]hen charging, the battery indicator lights up one by one, displaying increasing battery percentage from 25%, 50%, 75%, to 100%.” (Momcozy S12 Pro User Guide, p. 13.)

The Momcozy S12 Pro housing includes an air pump powered by the battery that generates negative air pressure. The Momcozy S12 Pro user guide also identifies that the housing has the “pump motor,” stating that “[t[he breast pump has 9 suction levels to choose from.” (Momcozy, S12 Pro User Manual, pp. 3, 5, 7.)</td></tr>
</table>

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

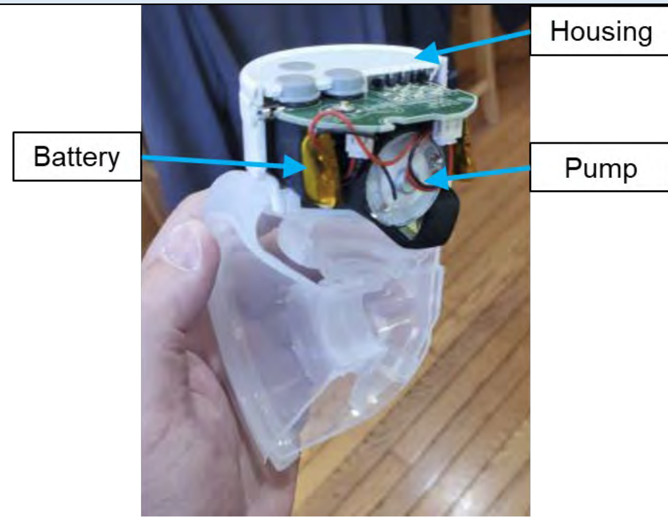
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12 Pro**
		 Momcozy S12 Pro internal components.

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

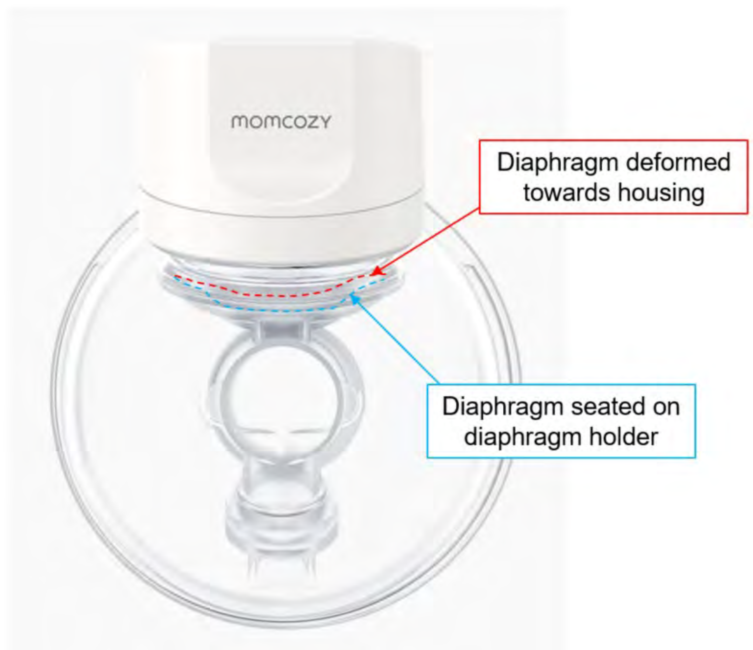
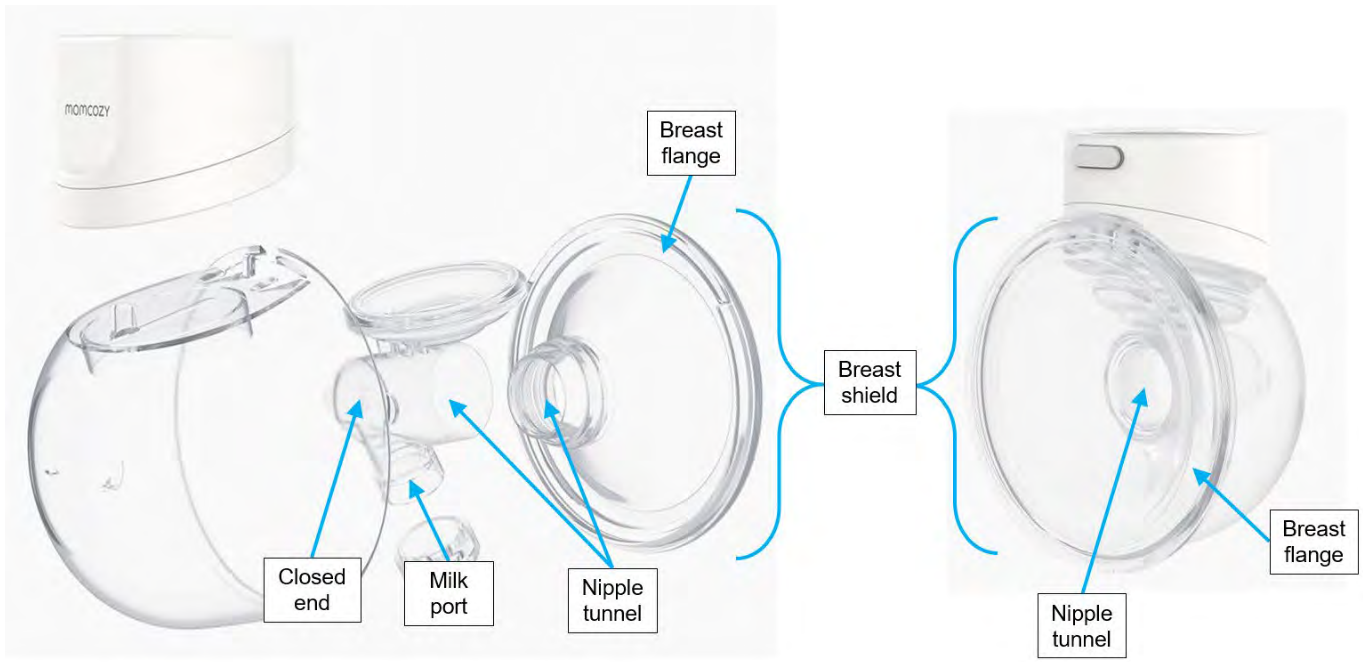
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S12 Pro**
		The Momcozy S12 Pro includes the diaphragm, which deforms in response to changes in air pressure caused by the air pump to create negative air pressure in the nipple tunnel. The Momcozy S12 Pro User Guide also identifies that "[t]he breast pump has 9 suction levels to choose from." (Momcozy, S12 Pro User Manual, p. 5.) On information and belief, when the pump is operated in the housing, it creates a change in air pressure that deforms the diaphragm to create negative pressure in the nipple tunnel. 

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

<table>
<tr><th colspan="3">The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy S12 Pro</th></tr>
<tr><td>1.3</td><td>a breast shield comprising a breast flange and a nipple tunnel extending from the breast flange, the nipple tunnel comprising a closed end and a milk port intermediate to the breast flange and the closed end, and the breast shield being separate from the diaphragm; and</td><td>The Momcozy S12 Pro includes a breast shield comprising of a breast flange and a nipple tunnel.


(https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump.)

The Momcozy website indicates that the S12 Pro product includes a “silicone flange (24 mm).” (https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump?variant=42641714741446.)

The Momcozy S12 Pro’s nipple tunnel contains a closed end and a milk port intermediate between the breast flange and the closed end.</td></tr>
</table>

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

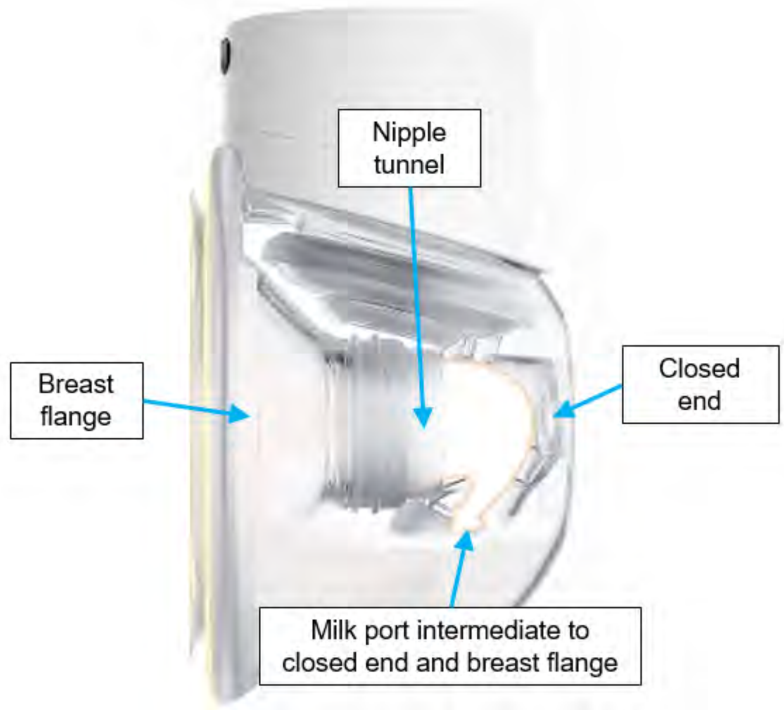
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S12 Pro**
		 The Momcozy S12 Pro contains a breast shield that is separate from the diaphragm.

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12 Pro**
		
1.4	a milk container that is configured to attach to the housing and receive expressed milk via the milk port.	The Momcozy S12 Pro includes a milk container that is configured to be attached to the housing and receive expressed milk via the milk port.

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12 Pro**
		 The Momcozy S12 Pro Quick Guide and User Guide also illustrates removal and assembly of the housing to the milk container. (Momcozy, S12 Pro Quick guide, p. 1; *See also* Momcozy, S12 Pro User Manual, pp. 9, 13.)

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

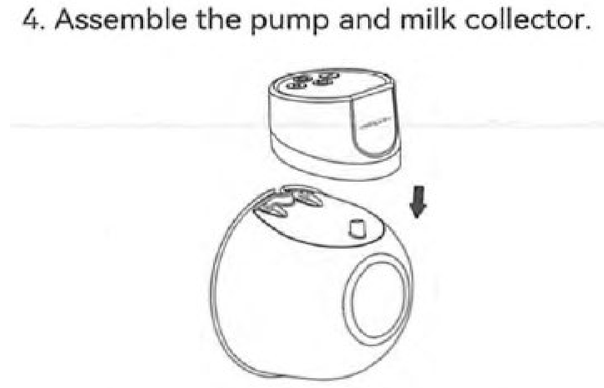
The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12 Pro**
		 The Momcozy 12 Pro’s milk container is configured to receive milk through the milk port.

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the '381 Patent.		
Claim Language		**Momcozy S12 Pro**
		 Momcozy Advertising material on Amazon.com (https://www.amazon.com/Momcozy-Wearable-Breast-Double-Levels/dp/B09VPRJ2S8?ref_=ast_sto_dp) Multiple user posts shown on the Momcozy website show breast milk received in the milk container as shown below.

Exhibit 30 – U.S. Patent No. 11,813,381 – Infringement Claim Chart for Momcozy 12 Pro Product

The Momcozy S12 Pro includes, literally or under the doctrine of equivalents, every element of claim 1 of the ’381 Patent.		
Claim Language		**Momcozy S12 Pro**
		Sabrinasabrina Verified 1/6/2023 ★★★★★ I bought this because I was tired being limited to sitting in one spot while pumping and not being able to move freely. I originally bought a Spectra pump as recommended by so many. It works great, but again I was tired of having to sit in one spot while pumping when I have so many things to do. I was originally hesitant to buy a hands free, wearable pump because I had heard a lot of women say the suction on these types of pumps was not strong enough to completely empty the breast. However, sinc...  https://momcozy.com/products/momcozy-s12-pro-wearable-breast-pump?variant=42641714741446

Exhibit 31

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

<table>
<tr><th colspan="3">The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy V1</th></tr>
<tr><td colspan="3">Claim 17</td></tr>
<tr><td>17.P</td><td>A breast pump system comprising:</td><td>The Momcozy V1 is a breast pump system. The Momcozy V1 is described as a “Hands-Free Breast Pump - Hospital Grade.” (https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade.)

(https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade.)</td></tr>
</table>

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

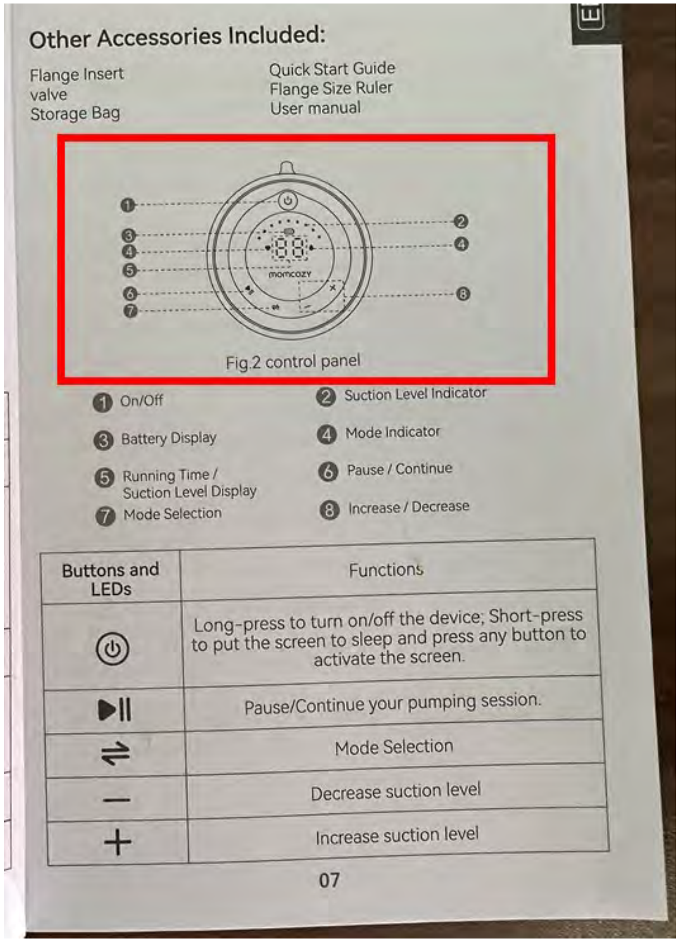
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V1**
		 (https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade.)

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

<table>
<tr><th colspan="3">The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy V1</th></tr>
<tr><td>17.1</td><td>a control unit comprising:

a battery, and

a pump configured to be powered by the battery and to generate negative air pressure; and</td><td>The Momcozy V1 includes a control unit. For example, the Momcozy V1 User Manual shows that the breast pump system includes a main unit with a control panel. (Momcozy V1 User Manual, p. 7.)



Other Accessories Included:
Flange Insert
valve
Storage Bag
Quick Start Guide
Flange Size Ruler
User manual

Fig.2 control panel

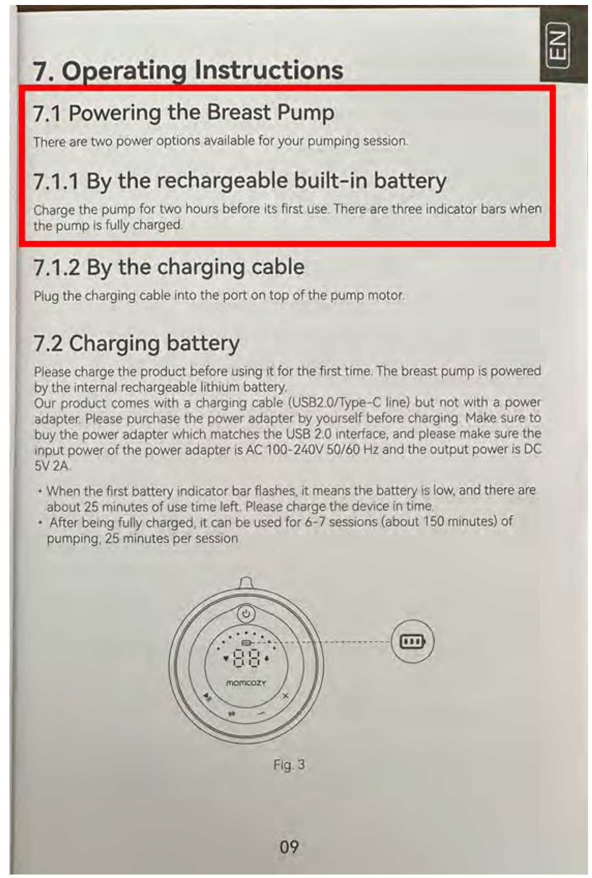
1 On/Off
2 Suction Level Indicator
3 Battery Display
4 Mode Indicator
5 Running Time / Suction Level Display
6 Pause / Continue
7 Mode Selection
8 Increase / Decrease

Buttons and LEDs | Functions
⏻ | Long-press to turn on/off the device; Short-press to put the screen to sleep and press any button to activate the screen.
▶II | Pause/Continue your pumping session.
⇌ | Mode Selection
— | Decrease suction level
+ | Increase suction level

07</td></tr>
</table>

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.	
Claim Language	**Momcozy V1**
	The Momcozy V1 User Manual shows that the breast pump system can be powered “[b]y the rechargeable built-in battery.” (Momcozy V1 User Manual, p. 9.)



EN

7. Operating Instructions

7.1 Powering the Breast Pump

There are two power options available for your pumping session.

7.1.1 By the rechargeable built-in battery

Charge the pump for two hours before its first use. There are three indicator bars when the pump is fully charged.

7.1.2 By the charging cable

Plug the charging cable into the port on top of the pump motor.

7.2 Charging battery

Please charge the product before using it for the first time. The breast pump is powered by the internal rechargeable lithium battery.
Our product comes with a charging cable (USB2.0/Type-C line) but not with a power adapter. Please purchase the power adapter by yourself before charging. Make sure to buy the power adapter which matches the USB 2.0 interface, and please make sure the input power of the power adapter is AC 100-240V 50/60 Hz and the output power is DC 5V 2A.

- When the first battery indicator bar flashes, it means the battery is low, and there are about 25 minutes of use time left. Please charge the device in time.
- After being fully charged, it can be used for 6-7 sessions (about 150 minutes) of pumping, 25 minutes per session.

Fig. 3

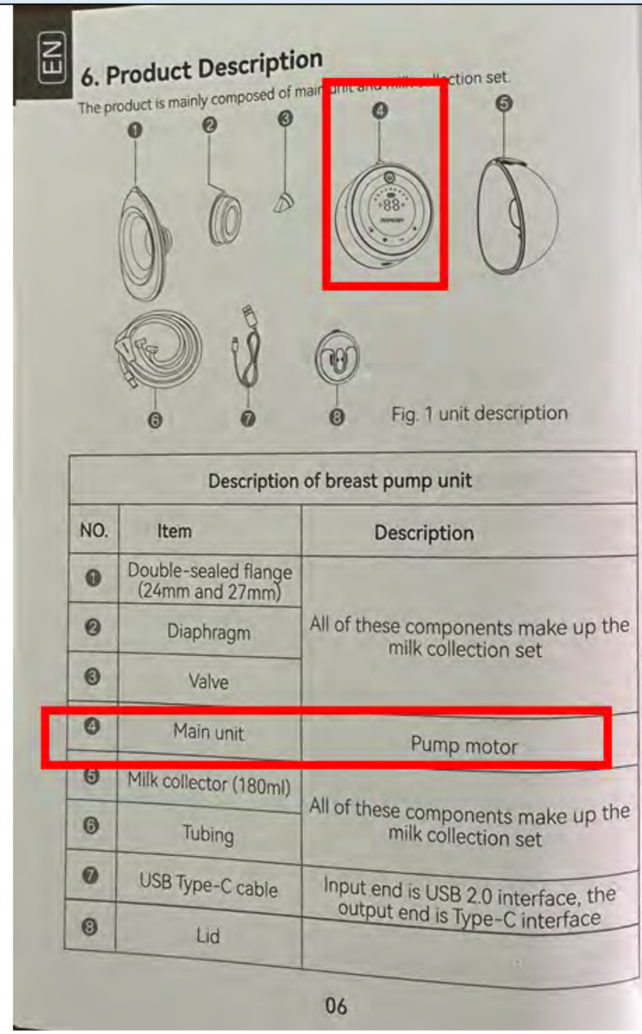
09

(Momcozy V1 User Manual, p. 9.)

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V1**
		 The Momcozy V1 User Manual shows that the “Main unit” (photographed above) includes a “Pump motor.” (Momcozy V1 User Manual, p. 6.)

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.	
Claim Language	**Momcozy V1**
	

Description of breast pump unit		
NO.	Item	Description
1	Double-sealed flange (24mm and 27mm)	All of these components make up the milk collection set
2	Diaphragm	
3	Valve	
4	Main unit	Pump motor
5	Milk collector (180ml)	All of these components make up the milk collection set
6	Tubing	
7	USB Type-C cable	Input end is USB 2.0 interface, the output end is Type-C interface
8	Lid	

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

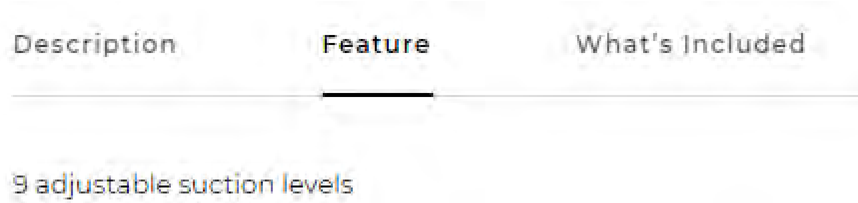
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V1**
		The Momcozy V1 product is advertised as having “9 adjustable suction levels.” (https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade (see below).) On information and belief, when the pump is operated in the control unit, the pump generates negative air pressure. 
17.2	a wearable milk collection hub configured to connect to the control unit via an air line, the wearable milk collection hub comprising:	The Momcozy V1 includes a wearable milk collection hub, as shown below.

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V1**
		 The Momcozy V1 is described as a “hands-free wearable breast pump.” (https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade.)

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.	
Claim Language	**Momcozy V1**
	Hands-free, compact and portable **Pump anywhere you want** Enjoy the convenient pumping with the hands-free wearable breast pump (one milk collector weighs only 120g/0.26lb). Designed for busy moms on the go, this wearable breast pump is portable and compact, making it easy to carry in your bag or purse. (https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade.)

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

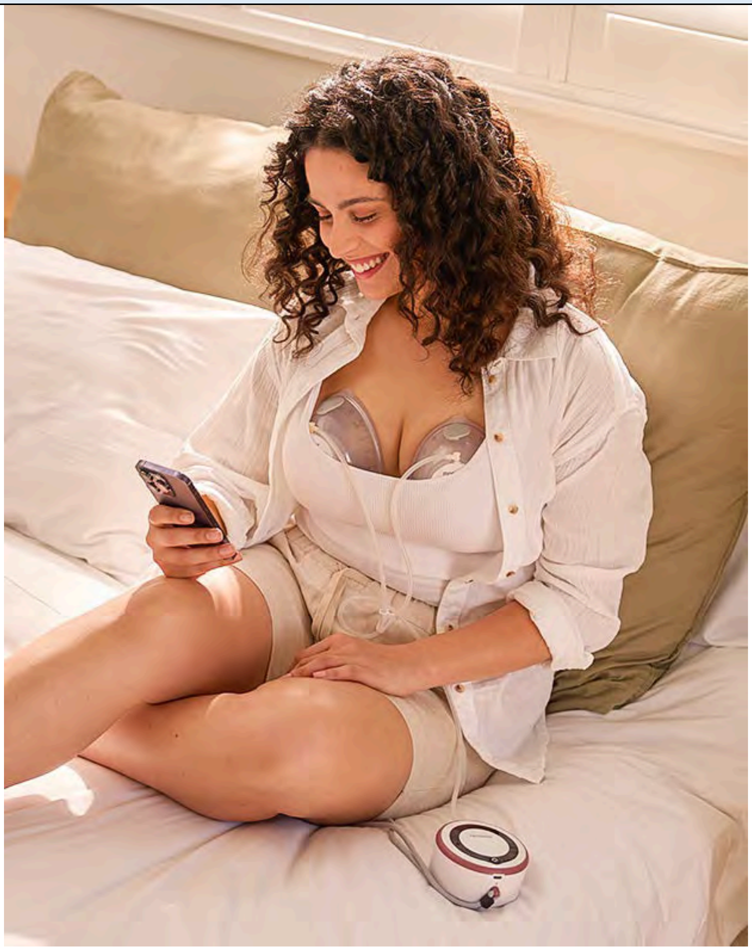
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		Momcozy V1
		 (https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade.)

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

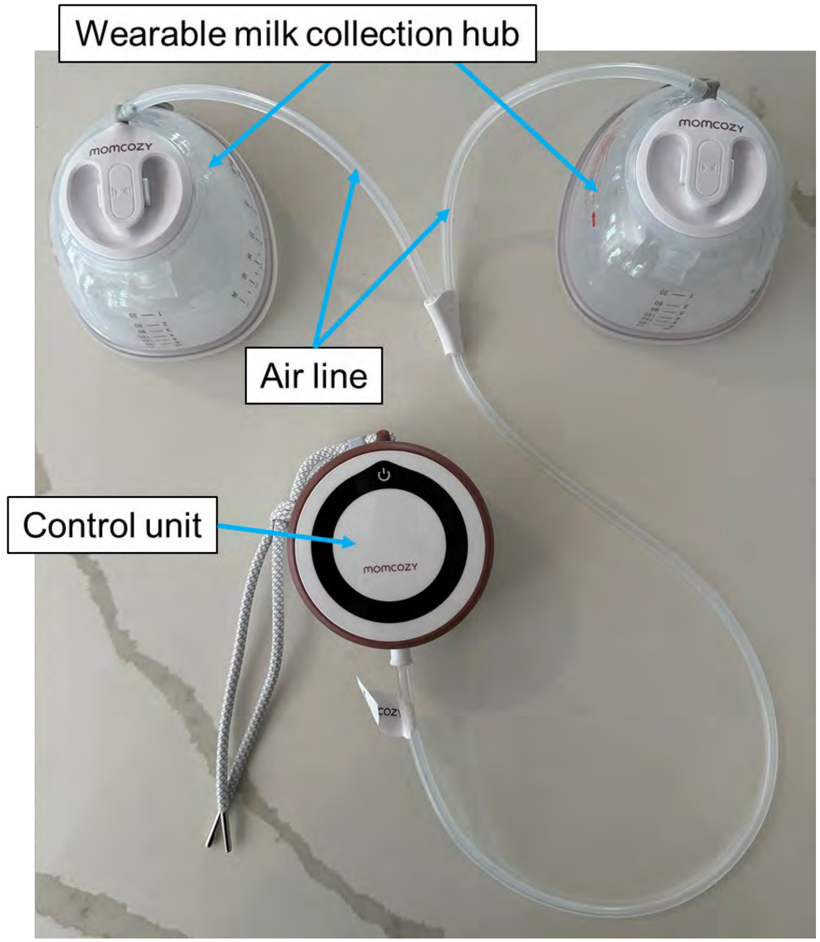
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V1**
		The wearable milk collection hub is configured to connect to the control unit via an air line. 

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V1**
17.3	a breast shield comprising: a breast flange; and a nipple tunnel extending from the breast flange;	The wearable milk collection hub includes a breast shield.  (https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade.)

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

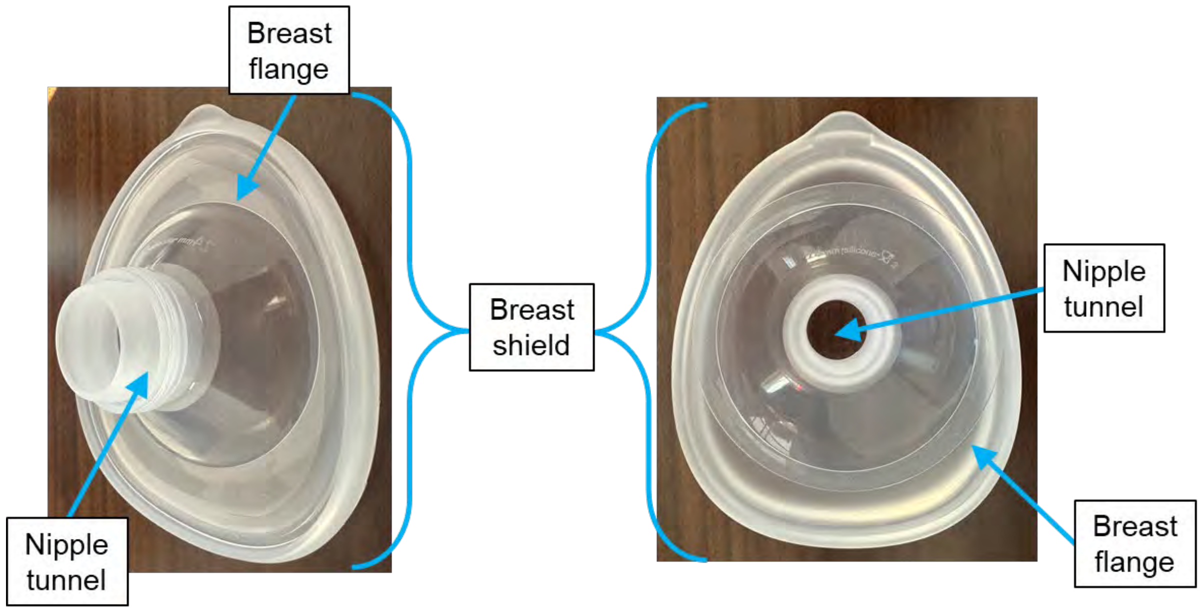
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V1**
		The breast shield includes a breast flange and a nipple tunnel extending from the breast flange. 

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

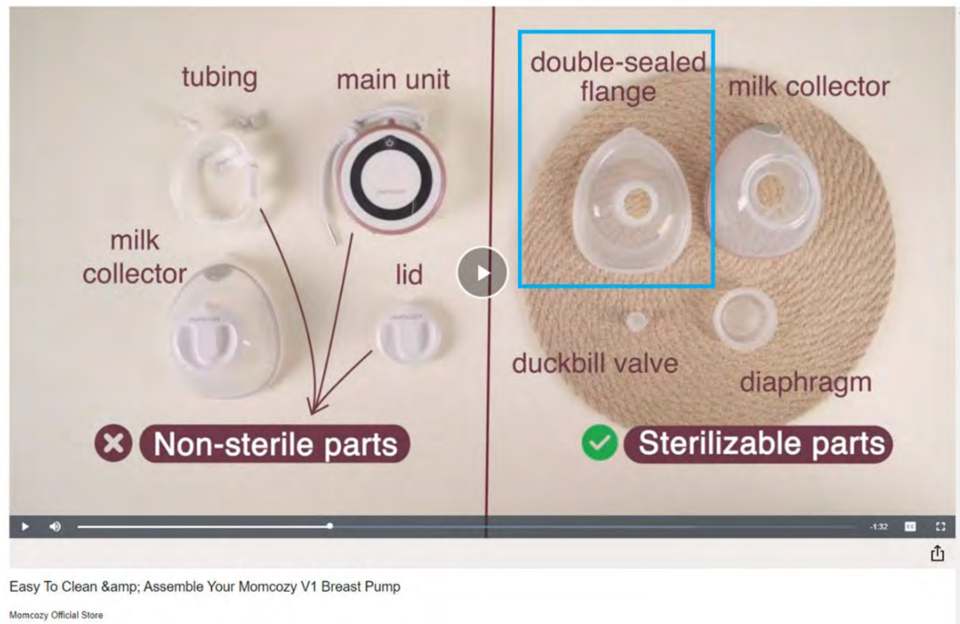
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V1**
		 (https://www.amazon.com/vdp/0343ad7a6bb64b678c1fa8b4e9d72973?product=B0C1P6CC2W&ref=cm_sw_em_r_ib_dt_J8eGEtINfUwiy.)
17.4	a diaphragm configured to deform based on the negative air pressure generated by the pump to create	The wearable milk collection hub includes a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel. The Momcozy V1 product is advertised as having "9 adjustable suction levels." (https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade.) On information and belief, when the pump is operated in the control unit, and when the control unit is connected to the wearable milk

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

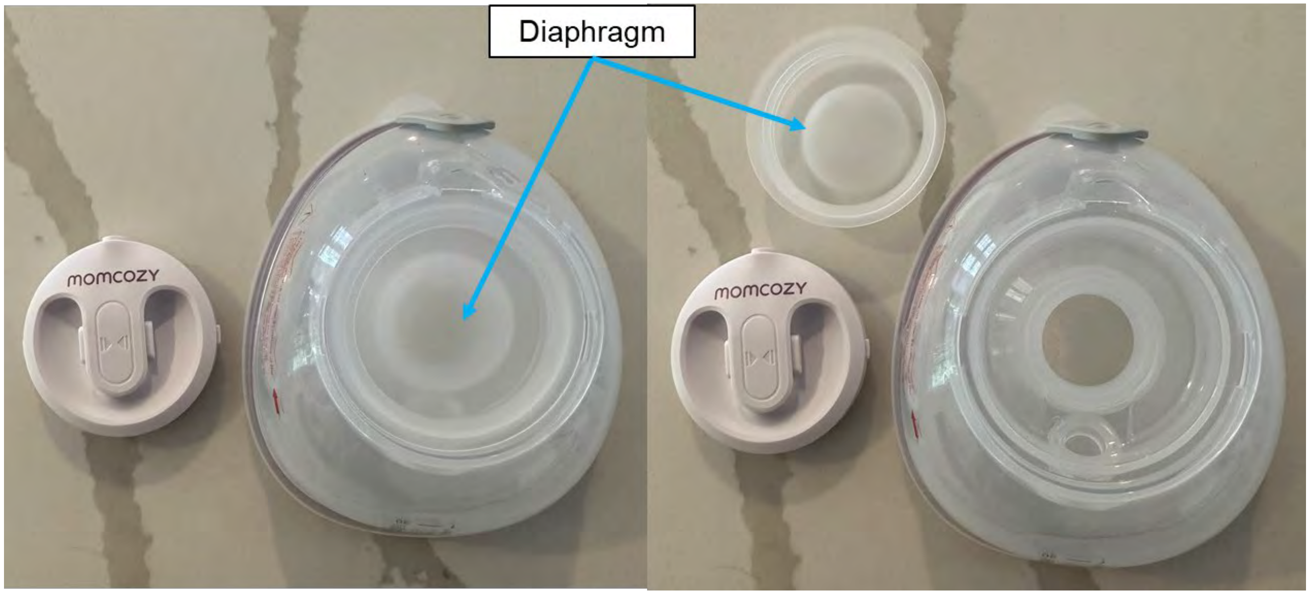
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V1**
	negative air pressure in the nipple tunnel;	collection hub in the an air line, it creates a change in air pressure that deforms the diaphragm to create negative pressure in the nipple tunnel. 

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

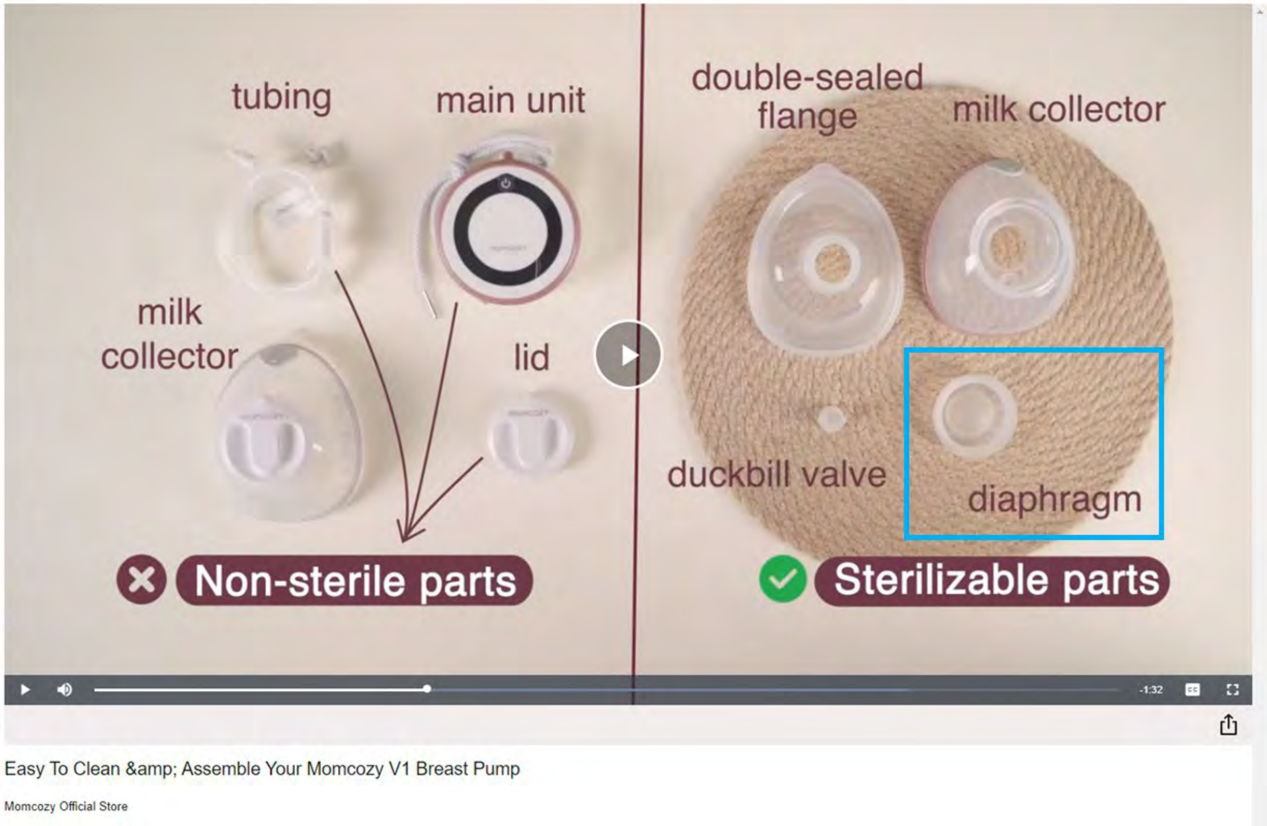
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V1**
		 (https://www.amazon.com/vdp/0343ad7a6bb64b678c1fa8b4e9d72973?product=B0C1P6CC2W&ref=cm_sw_em_r_ib_dt_J8eGEtINfUwiy.)

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V1**
17.5	an outer shell comprising a rear end configured to removably attach to the breast shield and, an interior volume between the outer shell and the breast shield defining a chamber to receive expressed milk; and	The wearable milk collection hub includes an outer shell comprising a rear end.  As shown below, the outer shell is configured to removably attach to the breast shield.

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

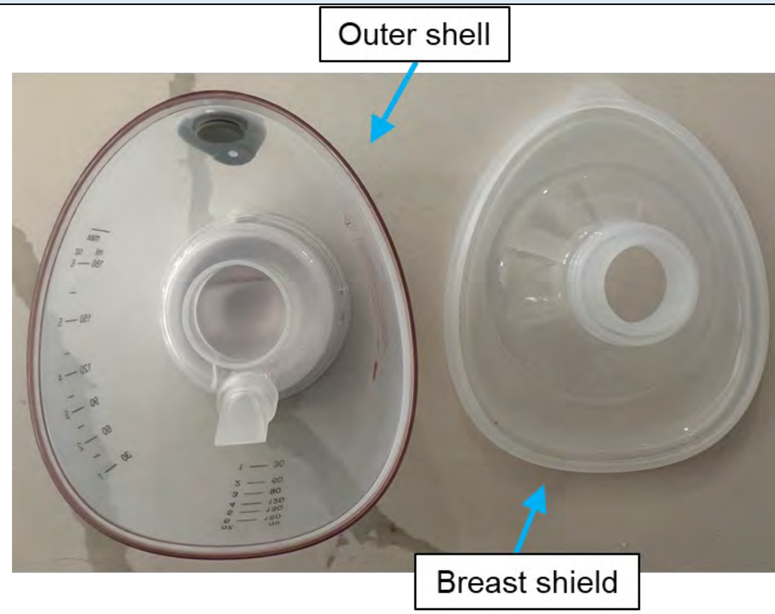
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.	
Claim Language	**Momcozy V1**
	 When the breast shield is attached to the outer shell, an interior volume is formed between the outer shell and the breast shield. This interior volume is a chamber for receiving expressed milk. This is illustrated in the image below, which shows milk in the chamber.

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V1**
		 (https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade.) The Momcozy V1 is advertised as having a "Container Capacity: 7.7 oz." (https://momcozy.com/products/v1-hands-free-breast-pump-hospital-grade.)
17.6	a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell, the front end being opposite to the rear end, the diaphragm cap forms a central region on a front surface of the outer shell.	The wearable milk collection hub includes a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell.

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

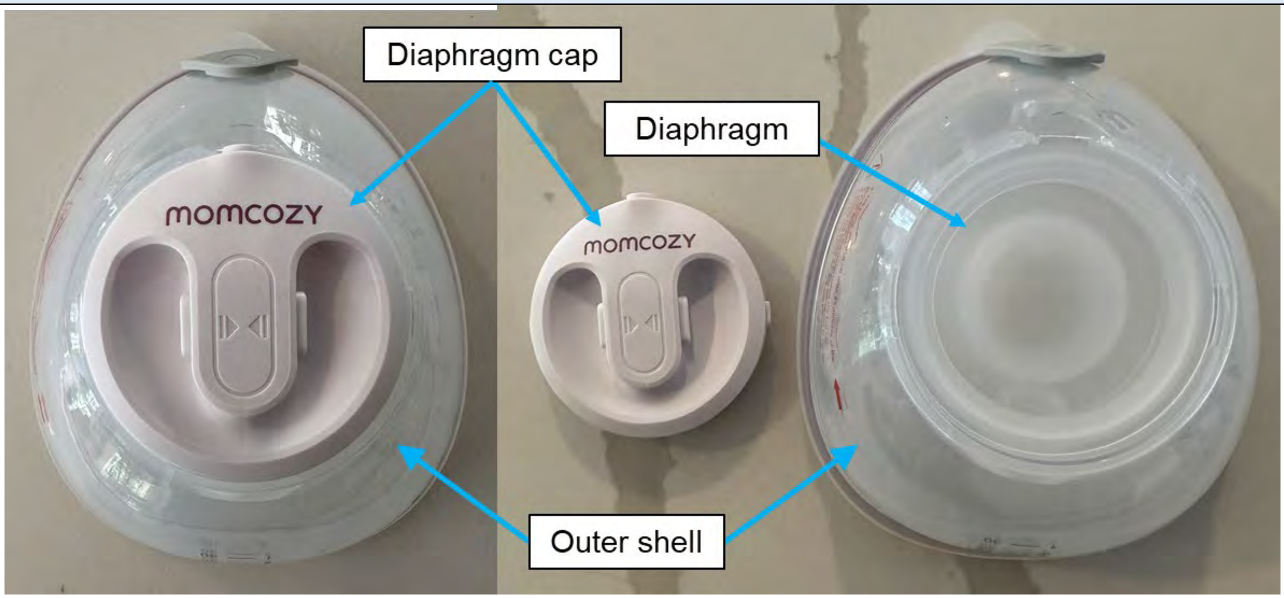
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V1**
		 The Momcozy V1 User Manual instructs the user to “Attach the diaphragm with the milk collector and secure the lid *to form a tight seal*.” (Momcozy V1 User Manual, p. 21 (emphasis added).)

Exhibit 31 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V1 Product

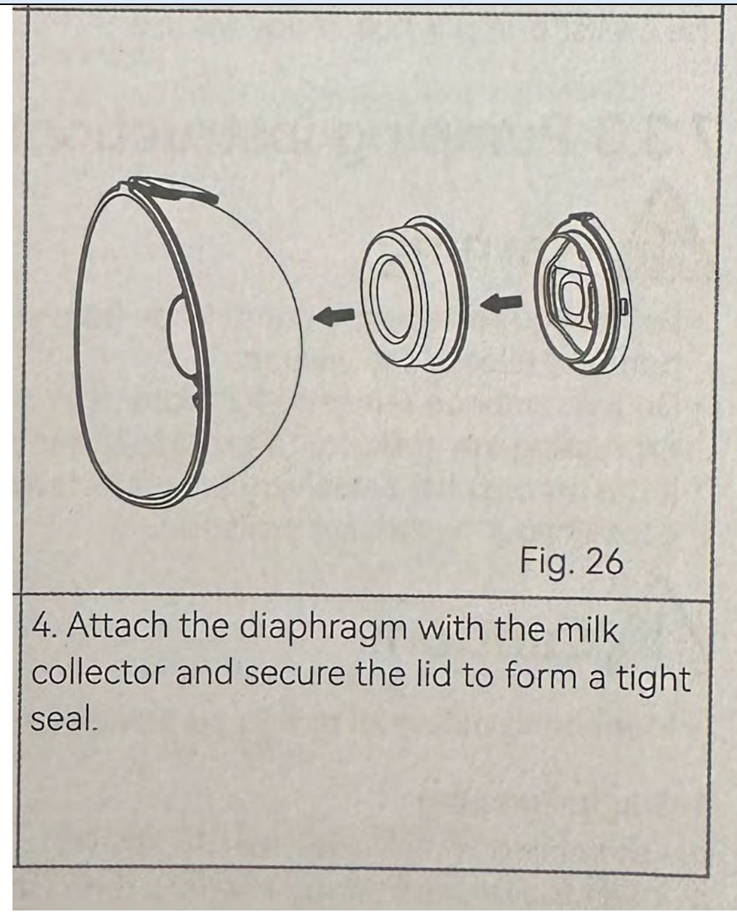
The Momcozy V1 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.	
Claim Language	**Momcozy V1**
	 (Momcozy V1 User Manual, p. 21.)

Exhibit 32

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V2**
Claim 17		
17.P	A breast pump system comprising:	The Momcozy V2 is a breast pump system. The Momcozy V2 is described as a "Hands-Free Breast Pump - Ultra-light & Potent." (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent.)  (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent.)

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V2**
		 (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent.)

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

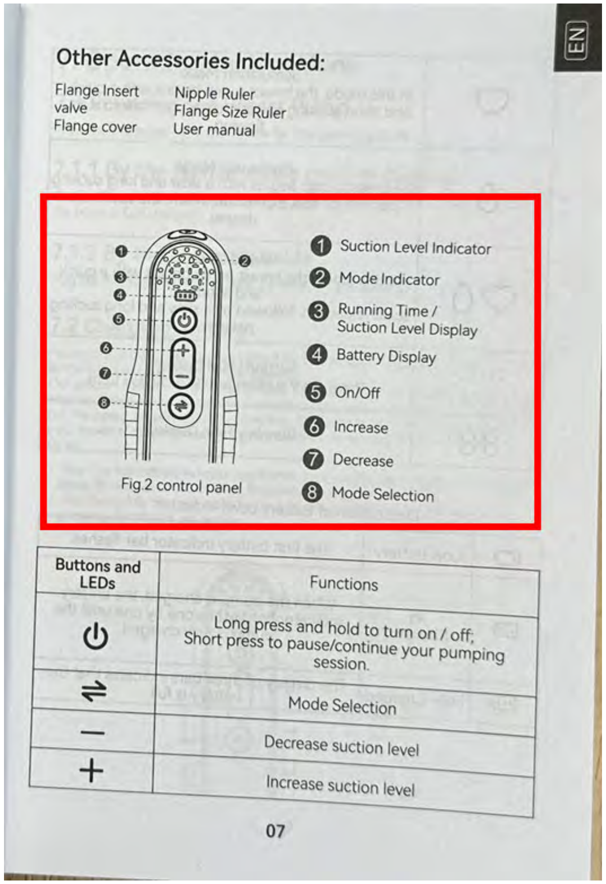
The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V2**
17.1	a control unit comprising: a battery, and a pump configured to be powered by the battery and to generate negative air pressure; and	The Momcozy V2 includes a control unit. For example, the Momcozy V2 User Manual shows that the breast pump system includes a main unit with a control panel. (Momcozy V2 User Manual, p. 7.) 

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

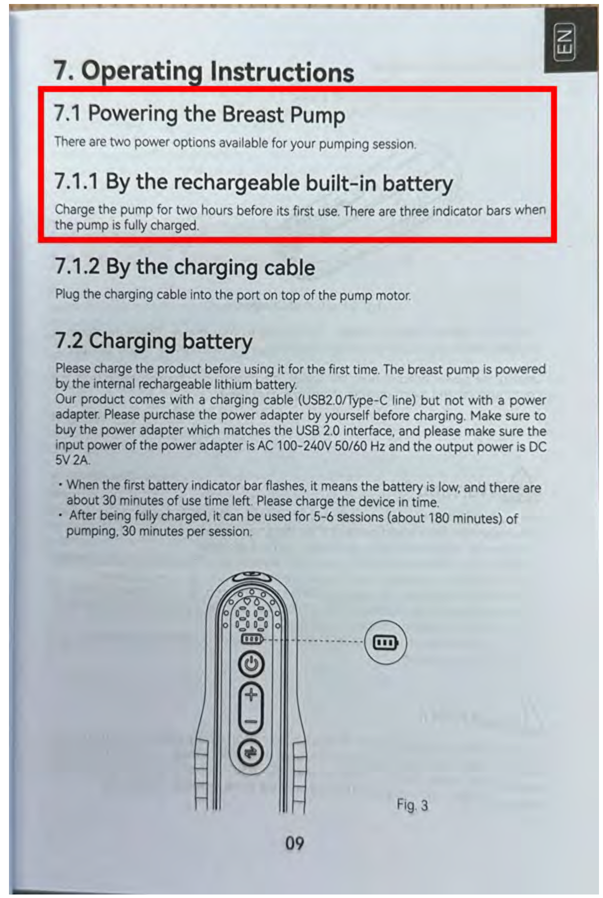
The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.	
Claim Language	**Momcozy V2**
	The Momcozy V2 User Manual shows that the breast pump system can be powered "[b]y the rechargeable built-in battery." (Momcozy V2 User Manual, p. 9.)  EN 7. Operating Instructions 7.1 Powering the Breast Pump There are two power options available for your pumping session. 7.1.1 By the rechargeable built-in battery Charge the pump for two hours before its first use. There are three indicator bars when the pump is fully charged. 7.1.2 By the charging cable Plug the charging cable into the port on top of the pump motor. 7.2 Charging battery Please charge the product before using it for the first time. The breast pump is powered by the internal rechargeable lithium battery. Our product comes with a charging cable (USB2.0/Type-C line) but not with a power adapter. Please purchase the power adapter by yourself before charging. Make sure to buy the power adapter which matches the USB 2.0 interface, and please make sure the input power of the power adapter is AC 100-240V 50/60 Hz and the output power is DC 5V 2A. • When the first battery indicator bar flashes, it means the battery is low, and there are about 30 minutes of use time left. Please charge the device in time. • After being fully charged, it can be used for 5-6 sessions (about 180 minutes) of pumping, 30 minutes per session. Fig. 3 09 (Momcozy V2 User Manual, p. 9.)

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
	Claim Language	**Momcozy V2**
		 The Momcozy V2 User Manual shows that the "Main unit" (photographed above) includes a "Pump motor." (Momcozy V2 User Manual, p. 6.)

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

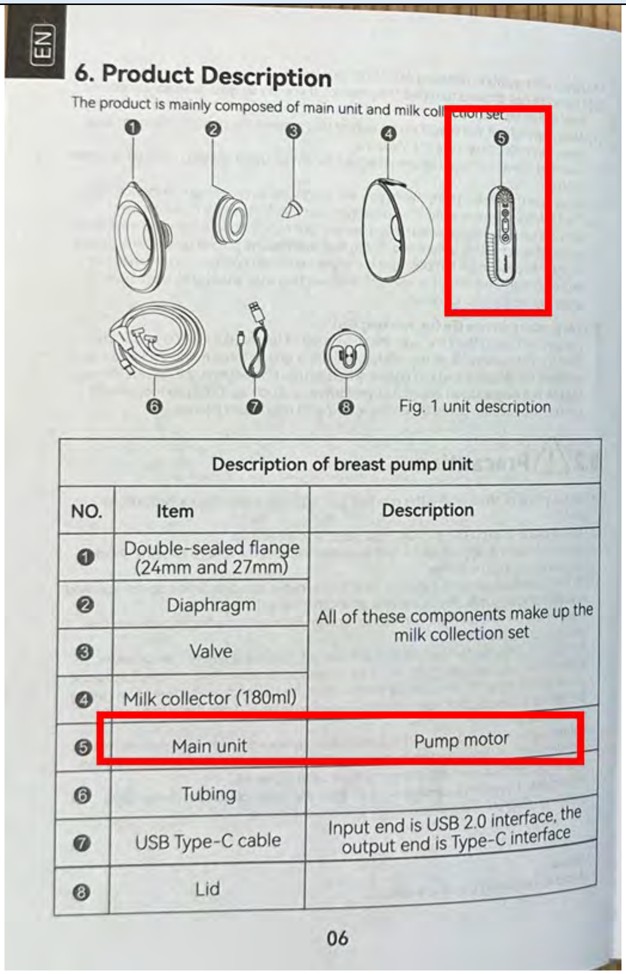
The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.	
Claim Language	**Momcozy V2**
	

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V2**
		The Momcozy V2 product is advertised as having “9 adjustable suction levels.” (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent (see below).) On information and belief, when the pump is operated in the control unit, the pump generates negative pressure. 
17.2	a wearable milk collection hub configured to connect to the control unit via an air line, the wearable milk collection hub comprising:	The Momcozy V2 includes a wearable milk collection hub, as shown below.

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V2**
		 The Momcozy website states that “[t]he V2 wearable breast pump is incredibly lightweight and portable.” (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent.)

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
	Claim Language	**Momcozy V2**
		Ultra-light & potent **Extremely Lightweight and Easily Portable** The V2 wearable breast pump is incredibly lightweight and portable, weighing only 120g each, allowing you to easily multi-task while pumping. With powerful suction up to -288 (±5) mmHG, it simulates the suckling of a baby, making your expressing milk sessions quick and easy. It's the perfect solution for moms who want to maintain their milk supply while enjoying great mobility. (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent.)

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V2**
		 (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent.)

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

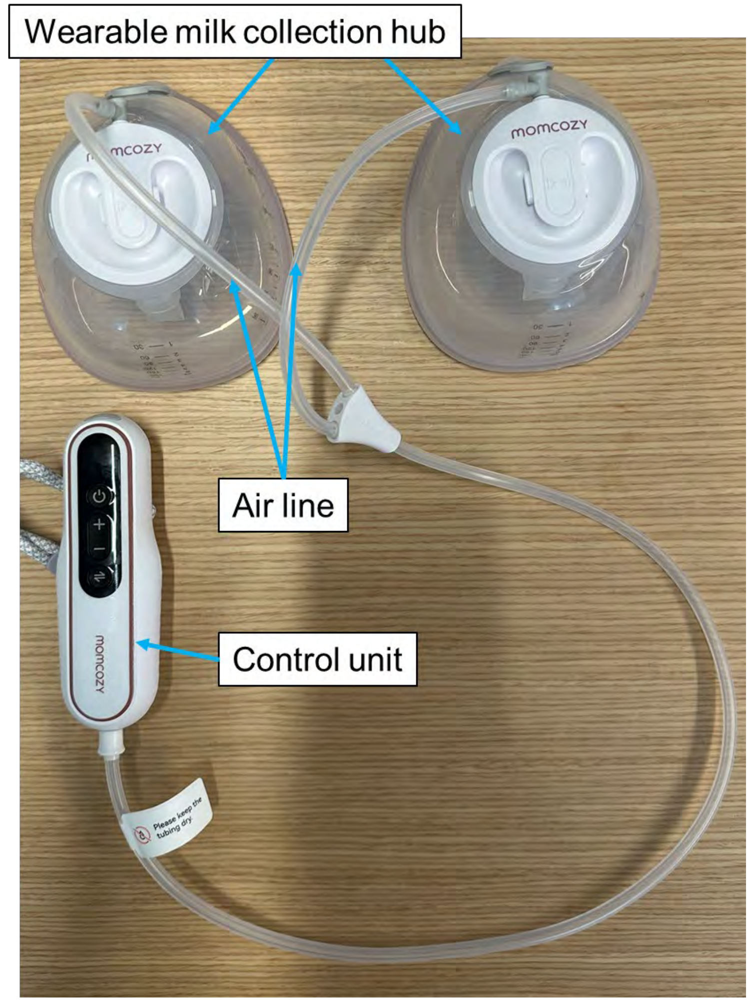
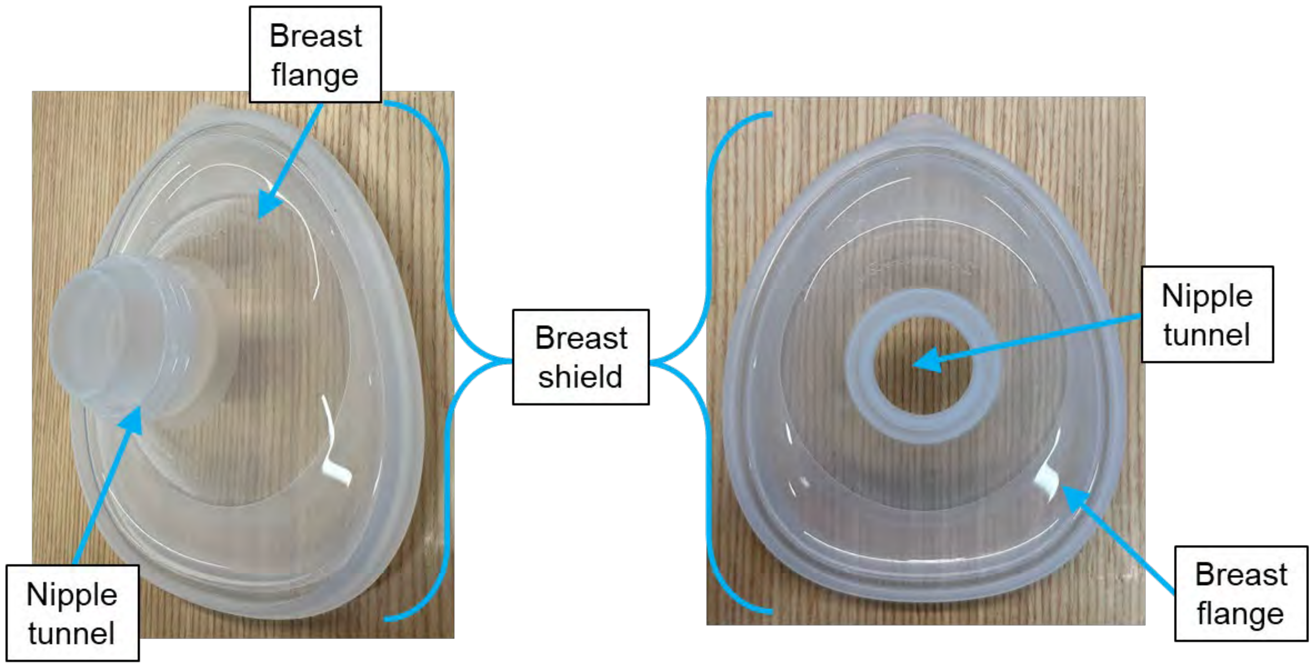
The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.	
Claim Language	**Momcozy V2**
	The wearable milk collection hub is configured to connect to the control unit via an air line. 

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

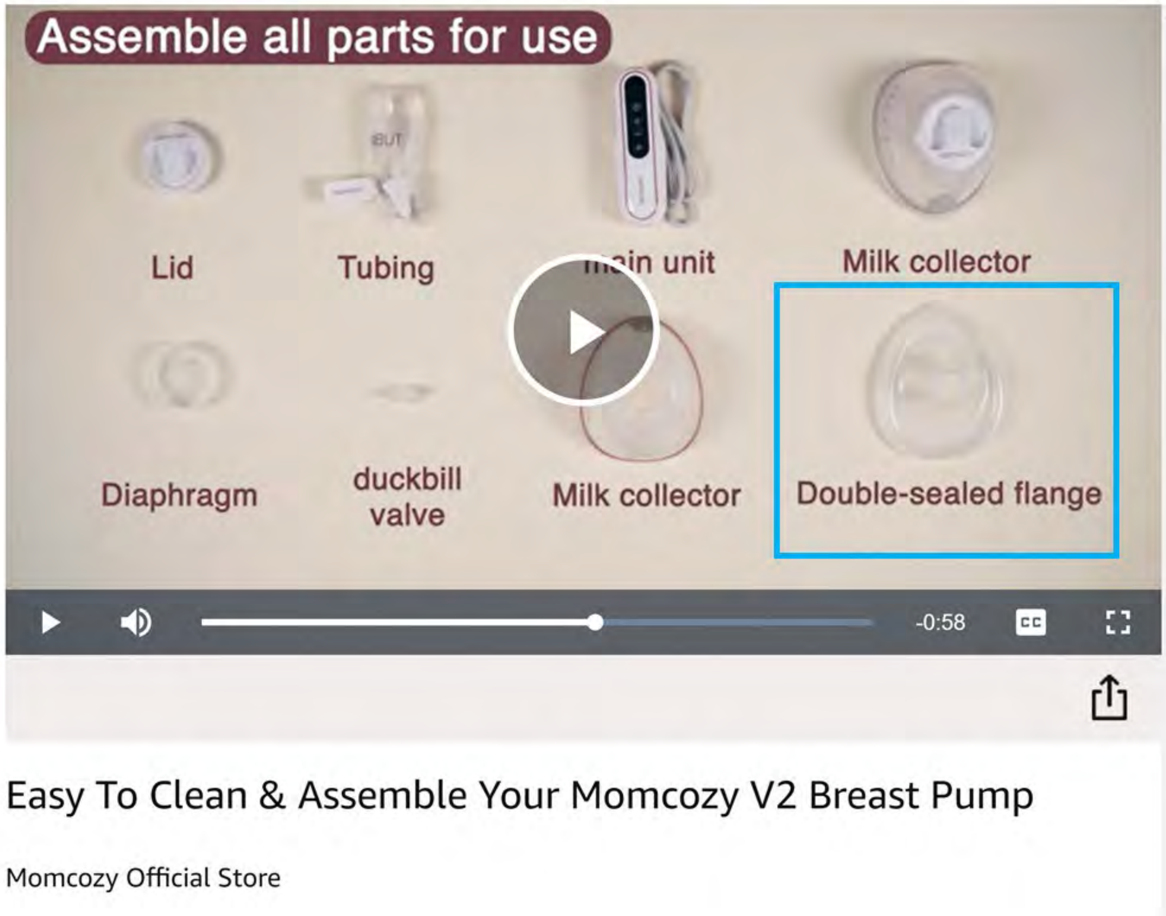
The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V2**
17.3	a breast shield comprising: a breast flange; and a nipple tunnel extending from the breast flange;	The wearable milk collection hub includes a breast shield.  (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent.)

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

<table>
<tr><th colspan="3">The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.</th></tr>
<tr><th colspan="2">Claim Language</th><th>Momcozy V2</th></tr>
<tr><td></td><td></td><td>The breast shield includes a breast flange and a nipple tunnel extending from the breast flange.


</td></tr>
</table>

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

<table>
<tr><th colspan="2">The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.</th></tr>
<tr><th>Claim Language</th><th>Momcozy V2</th></tr>
<tr><td></td><td>


(https://www.amazon.com/vdp/0ab25bdff50343b7858d93504eae543c?product=B0C1SR1TBY&ref=cm_sw_em_r_ib_dt_zY5sGhFGsJHMQ)
</td></tr>
</table>

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

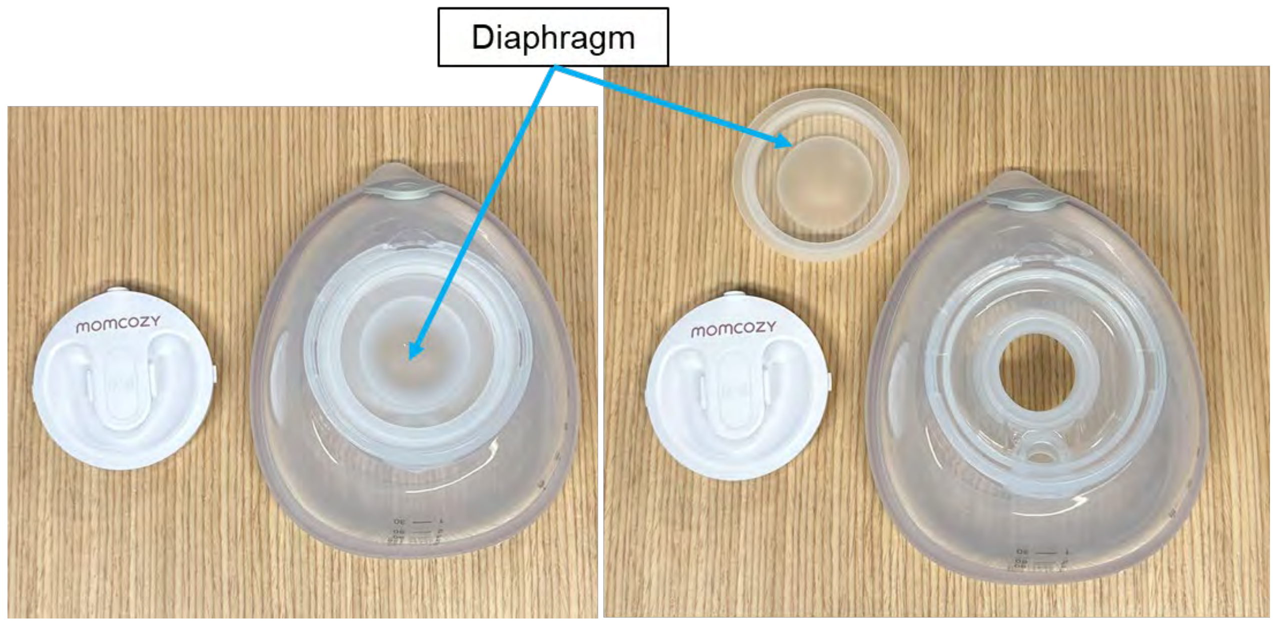
The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.		
Claim Language		**Momcozy V2**
17.4	a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel;	The wearable milk collection hub includes a diaphragm configured to deform based on the negative air pressure generated by the pump to create negative air pressure in the nipple tunnel. The Momcozy V2 product is advertised as having “9 adjustable suction levels.” (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent.) On information and belief, when the pump is operated in the control unit, and when the control unit is connected to the wearable milk collection hub the air line, creates a change in air pressure that deforms the diaphragm to create negative pressure in the nipple tunnel. 

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

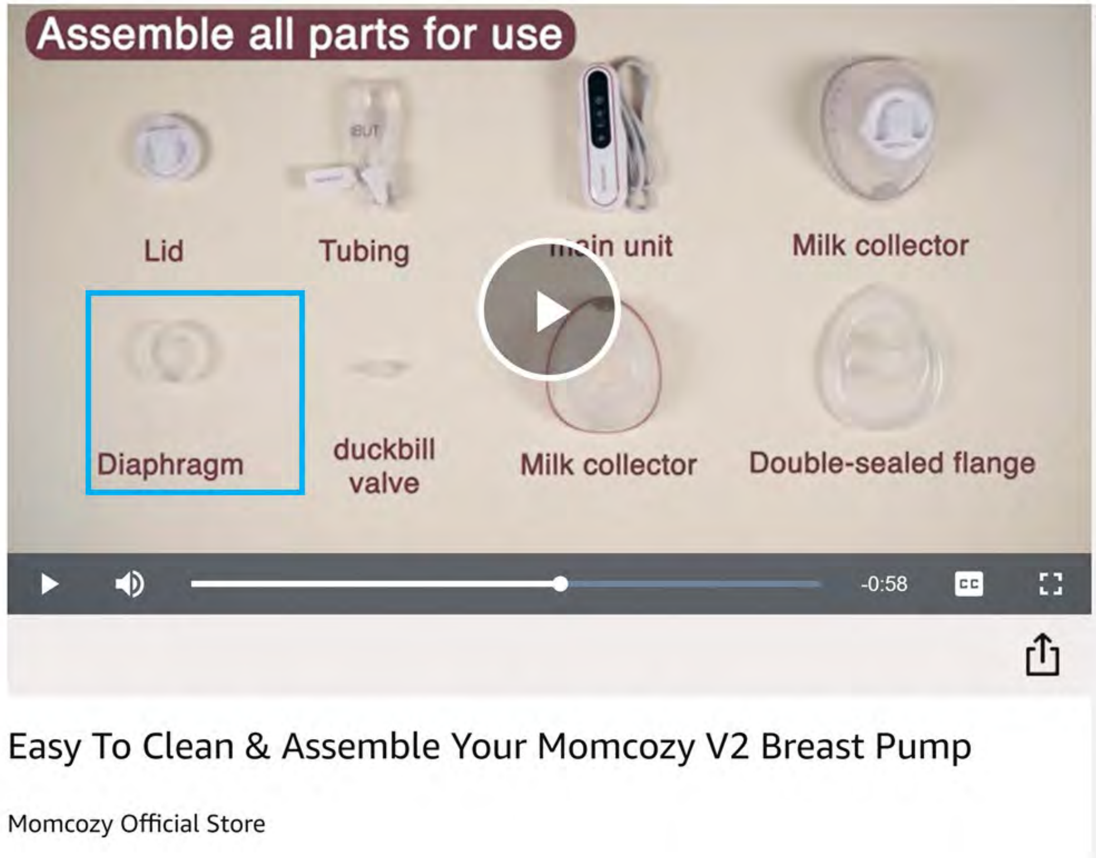
The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.	
Claim Language	**Momcozy V2**
	 (https://www.amazon.com/vdp/0ab25bdff50343b7858d93504eae543c?product=B0C1SR1TBY&ref=cm_sw_em_r_ib_dt_zY5sGhFGsJHMQ)

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V2**
17.5	an outer shell comprising a rear end configured to removably attach to the breast shield and, an interior volume between the outer shell and the breast shield defining a chamber to receive expressed milk; and	The wearable milk collection hub includes an outer shell comprising a rear end.  As shown below, the outer shell is configured to removably attach to the breast shield.

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

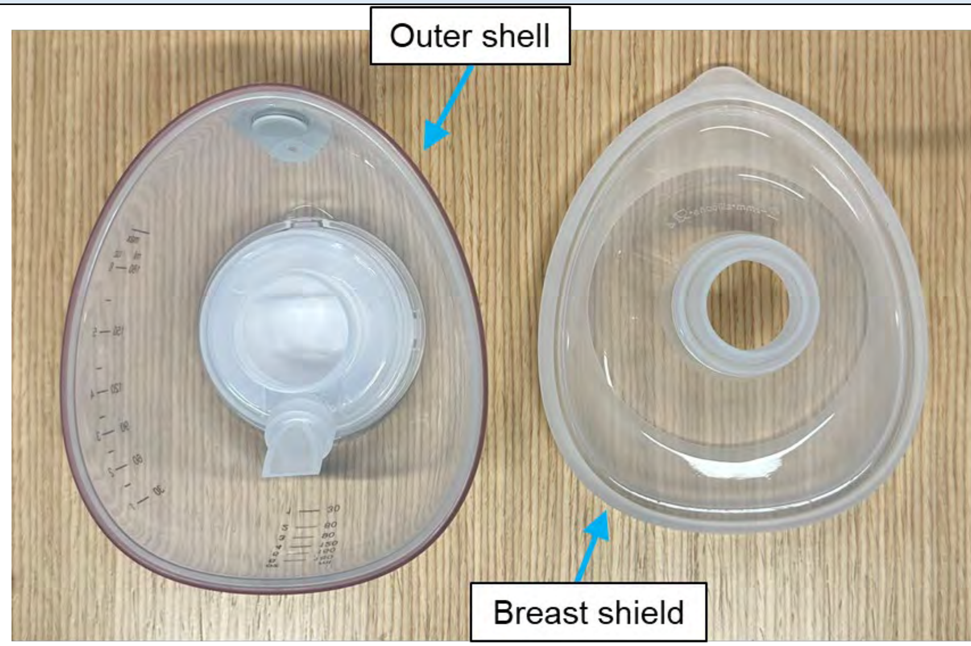
The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the ’454 Patent.	
Claim Language	**Momcozy V2**
	 When the breast shield is attached to the outer shell, an interior volume is formed between the outer shell and the breast shield. This interior volume is a chamber for receiving expressed milk. This is illustrated in the image below, which shows milk in the chamber.

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

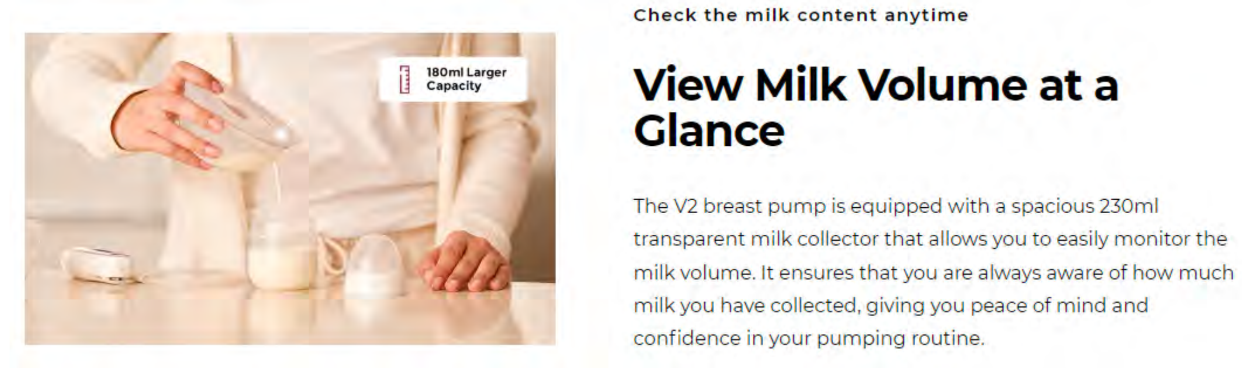
The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
	Claim Language	**Momcozy V2**
		 (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent.) The Momcozy V2 is advertised as having a "Container Capacity: 7.7 oz." (https://momcozy.com/products/v2-hands-free-breast-pump-ultra-light-potent.)
17.6	a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell, the front end being opposite to the rear end, the diaphragm cap forms a central region on a front surface of the outer shell.	The wearable milk collection hub includes a diaphragm cap configured to cover and seal the diaphragm at a front end of the outer shell.

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

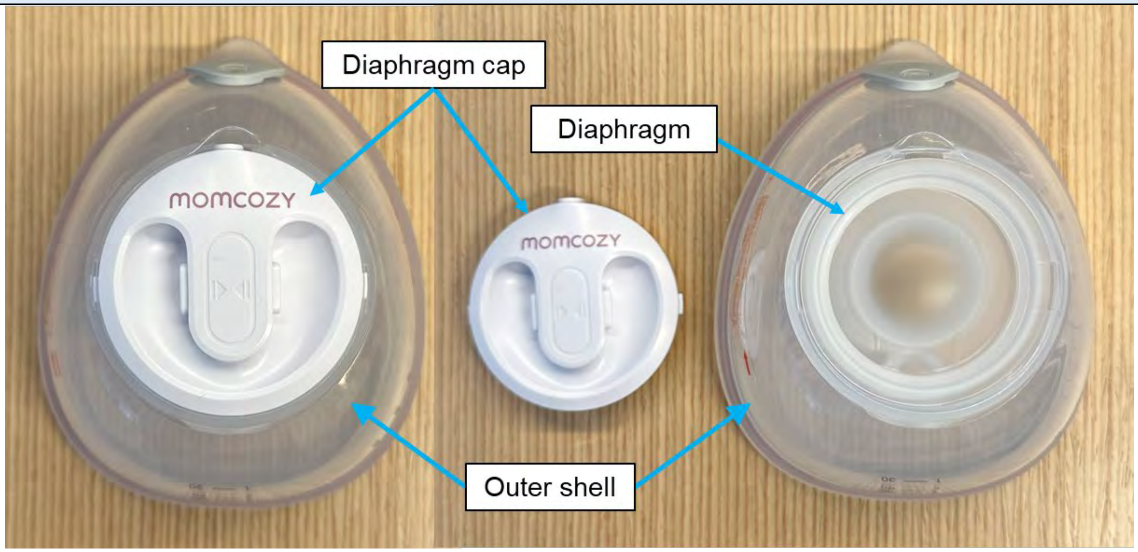
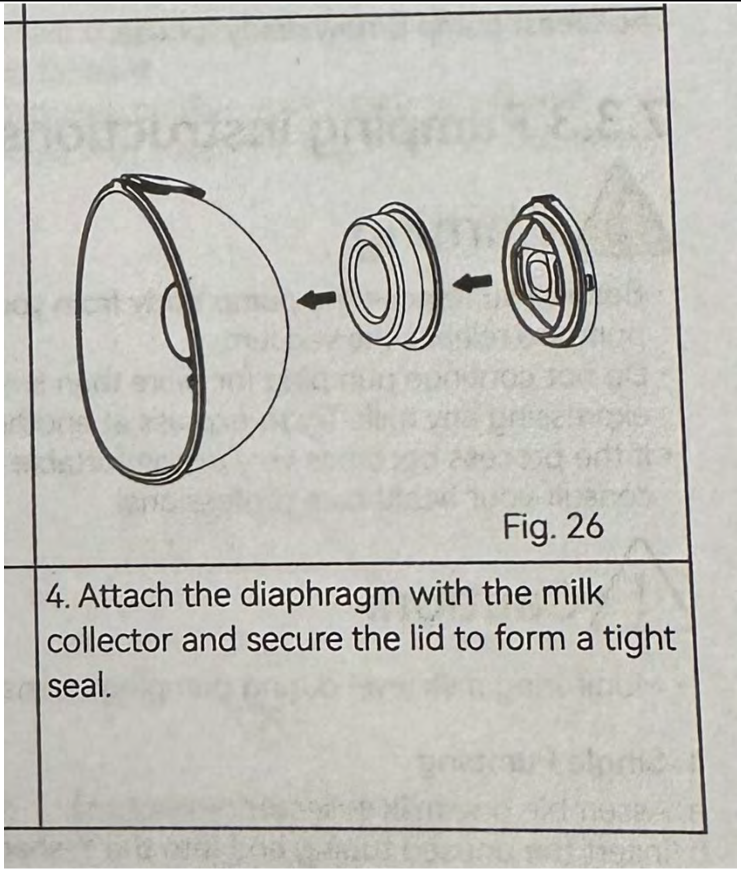
The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.		
Claim Language		**Momcozy V2**
		 The Momcozy V2 User Manual instructs the user to "Attach the diaphragm with the milk collector and secure the lid *to form a tight seal*." (Momcozy V2 User Manual, p. 21 (emphasis added).)

Exhibit 32 – U.S. Patent No. 11,806,454 – Infringement Claim Chart for V2 Product

The Momcozy V2 includes, literally or under the doctrine of equivalents, every element of claim 17 of the '454 Patent.	
Claim Language	**Momcozy V2**
	 (Momcozy V2 User Manual, p. 21.)